iPlus
SELECT CATEGORY
RESTORATIVE
SOFT TISSUE
ENDO
PERIO
IMPLANT
EXPANDED
BIOLASE
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waterlase

waterlase iPlus

User Manual
5200158 Rev. E (12/13)

BIOLASE

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Introduction

The Waterlase iPlus tissue cutting system is a unique device with diverse hard and soft tissue dental applications. For hard tissue procedures, the Waterlase iPlus utilizes advanced laser and water atomization technologies to safely and effectively perform tissue cutting, shaving, contouring, roughening, etching and resection. For soft tissue procedures, the Waterlase iPlus utilizes direct laser energy to perform tissue removal, incision, excision, ablation and coagulation. The Waterlase iPlus can also be used for endodontic and periodontal applications.

For hard tissue procedures, the YSGG solid-state laser provides optical energy to a user-controlled distribution of atomized water droplets and hydrated surface layer of hard tissue. Water in the spray, on tissue surface and within the surface tissue layer absorb laser radiation, resulting in explosive water expansion. Strong mechanical force from rapid water expansion induce separation of surface material, quickly and cleanly removing hard tooth tissue. A flexible fiber optic cable with handpiece delivers the unique laser wavelength and atomized distribution of water particles to the target tissue. A visible light emitted from the handpiece distal end pinpoints the area of treatment. The optical power output and atomized water spray may be adjusted to specific user requirements for both soft and hard tissue applications.

In soft tissue mode, the Waterlase iPlus is programmed to perform tissue removal, incision, excision, ablation and coagulation using direct laser energy either with or without water for cooling and hydration. The Waterlase iPlus system may also include the iLase diode laser, a surgical device designed for a wide variety of dental soft tissue procedures. For more information about the iLase, please refer to the iLase user manual (Biolase P/N 5400230).

Use of this device requires proper clinical and technical training. This manual provides instructions for use for trained dental surgeons and practitioners.

When used and maintained properly, the Waterlase iPlus will prove a valuable addition to your practice. Please contact your authorized local Biolase representative if you have any questions or require assistance.

1 Safety with the Waterlase

PRECAUTIONS

Failure to comply with these precautions and warnings may lead to exposure to dangerous voltage levels or optical radiation sources. Please comply with all safety instructions and warnings.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

DANGER: Invisible and/or visible laser radiation – Avoid eye or skin exposure to direct or scattered radiation. Class IV.

CAUTION: This unit has been designed and tested to meet or exceed the requirements of severe electromagnetic, electrostatic and radio frequency interference testing. However, the possibility of electromagnetic or other interference may still exist.

DANGER: Do not use this unit in any manner other than described herein. Do not use the unit if you suspect it is functioning improperly.

SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

1. Remove or cover all highly reflective items in the treatment area, if possible.

2. Do not operate in the presence of explosive or flammable materials.

3. All persons present in the operatory must wear protective eyewear suitable for blocking 940nm and

CAUTION: Periodically inspect eyewear for pitting and cracking.

NOTE: For replacement or additional protective eyewear, please contact your Waterlase iPlus representative.

4. Do not look directly into the beam or at specular reflections.

5. Direct the cutting spray toward targeted tissues only.

6. Press STANDBY (Standby button) on the control panel before changing water and before turning off the unit.

7. Move the circuit breaker to OFF (0) position (located on rear panel) and remove the key before leaving unit unattended.

DANGER: DO NOT open system side doors. These are to be used by authorized service personnel only. Danger from radiation exposure and high voltage may exist.

All operatory entrances must be marked with an approved warning sign indicating a laser is in the operatory.

8. PLUME REMOVAL

CAUTION: Laser plume may contain viable tissue particulates.

Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue during procedures done with laser and minimal or no water spray. Ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriate masks, and other protective equipment) is used at all times during procedures with this laser device.

SAFETY FEATURES

ENERGY MONITOR

The energy monitor measures and verifies power output. Power deviations of more than 20% from the selected value will cause the display to show an error message.

The unit will not operate until the system is reset by pressing the "Next" button on the touch screen. If error messages persist please contact your Representative.

CIRCUIT BREAKER

The circuit breaker on the back panel serves as a line switch to separate the unit from the main power supply (0 = OFF, 1 = ON).

KEYSWITCH

To switch unit ON, turn key to horizontal position. Use the proper key only. The key cannot be removed while in the ON position.

Always remove the key when the unit is left unattended for a long time.

FOOTSWITCH

The Waterlase iPlus will not activate until the user presses down on the footswitch. A protective cover prevents unintentional pressing of the footswitch. The protective cover can be opened or closed by pressing it from the top.

REMOTE INTERLOCK OUTLET

Each laser has a remote plug and connector on its rear panel. The purpose is to enable a user-provided remote switch (e.g., on the entrance door) to turn OFF the laser. To use it properly requires a normally-closed pair of contacts connected to pins 1 and 5 of the connector. These contacts should have no voltage associated with them and should open on activation.

Your Biolase service engineer can assist you in connecting the remote interlock to a door switch.

EMERGENCY STOP

Press the red emergency stop button to instantly turn off the unit. The button will glow red to indicate an emergency stop, and the control panel will display an error message.

Press the button again to restart the system. If the system was on when the emergency stop was activated, the system will be in standby mode when turned back on. You must push the "ready" button before using the system again.

CONTROL PANEL

The touch screen control panel shows the functional conditions of the system.

LAYOUT OF CONTROL ELEMENTS

All control functions are located at a safe distance from energy output. Control panel layout and instructions are described in Section 5, Operating Instructions.

Please refer to iLase User Manual for safety features associated with the iLase.

NOTE: Please direct any safety questions to your local Biolase representative, or call Biolase at (888) 4-BIOLASE [(888) 424-6527], or Biolase Service at (800) 321-6717

2 Installation

INSTALLATION INSTRUCTIONS

Your local authorized representative will unpack the Waterlase iPlus and your service representative will install the unit. Please leave all crates and shipping containers unopened until your trained service representative arrives. Complete installation, testing and demonstration requires approximately one full day.

The Waterlase iPlus must be installed with a qualified Biolase employee or representative; please refer to Section 4, Setup Instructions, for setup instructions.

Please contact your representative before transporting unit to a different location. Misalignment of optical components may occur during transportation if the unit is not properly packaged.

FACILITY REQUIREMENTS

ELECTRICAL SUPPLY: 100 VAC @ 15.0 Amps to 230 VAC @ 8.0 Amps, 50/60 Hz

COMPRESSED AIR SUPPLY: 80 - 120 psi (5.5 - 8.2 bar)

CAUTION: Moisture in the air supply line may damage the laser system. Please provide proper filtration to eliminate all moisture from air source.

Connections for air supply must be available in each operatory.

Attach air hose with 1/4” inside diameter male quick connectors on each end between air inlet connector and operatory air source.

CAUTION: Prior to connection, verify that outlet is for air, not water supply. Connection to water supply may cause damage to the Waterlase iPlus system. If the unit was connected to the water supply, do NOT turn the system on. Contact your service representative.

3 Equipment Description

GENERAL

The Waterlase iPlus dental laser system consists of three modules:

- Main Unit (the Unit – shown in Figures 2.1, 2.2, and 2.3)
- Waterlase iPlus Fiber Delivery System (the Delivery System – shown in Figures 2.1, 2.2, and 2.3)
- iLase Diode Laser Handpiece (optional).

MAIN UNIT ELEMENTS

Figures 2.1, 2.2, and 2.3 show the front, rear and top views of the unit.

CONTROL PANEL

The main unit is controlled through a touch screen control panel. Please see section 5, Operating Instructions, for detailed instructions on using the control panel.

FRONT AND BACK HANDLES

Use the front and back handles to move the unit and lift when necessary.

CAUTION: Prior to lifting, make sure handles are not damaged. Do not use the delivery system to pull the unit; this could damage the fiber optic and render the unit inoperable.

LOCKING WHEELS

Press down on front tabs to lock the unit. Lift up the tabs to release locking mechanism.

EMERGENCY STOP

Press the red emergency stop button to instantly turn off the unit. The button will glow red to indicate an emergency stop, and the control panel will display an error message. Press the button again to restart the system. If the system was on when the emergency stop was activated, the system will be in standby mode when turned back on. You must push the "Ready" key before using the system again.

KEY SWITCH

To switch unit ON, turn key to horizontal position. Use the proper key only. The key cannot be removed while in the ON position.

FOOTSWITCH CONNECTOR

Connect and secure footswitch here.

REMOTE INTERLOCK OUTLET

Each laser has a remote plug and connector on its rear panel. The purpose is to enable a user-provided remote switch (e.g., on the entrance door) to turn OFF the laser. To use it properly requires a normally-closed pair of contacts connected to pins 1 and 5 of the connector. These contacts should have no voltage associated with them and should open on activation.

Customers may request that the remote interlock be connected to a door switch.

(continued)

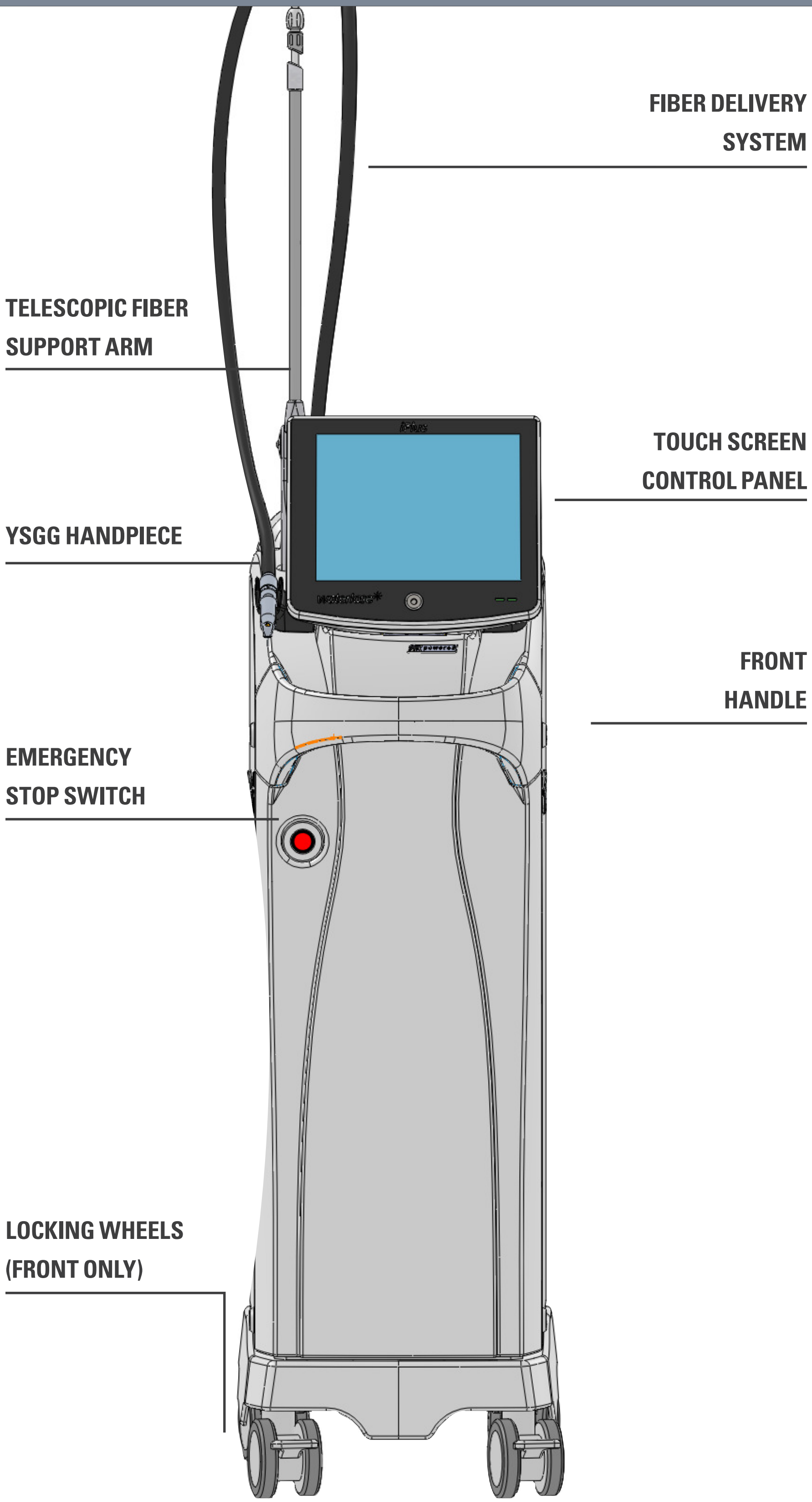

FIBER DELIVERY SYSTEM
TELESCOPIC FIBER SUPPORT ARM
TOUCH SCREEN CONTROL PANEL
YSGG HANDPIECE
FRONT HANDLE
EMERGENCY STOP SWITCH
LOCKING WHEELS (FRONT ONLY)

FIG 2.1

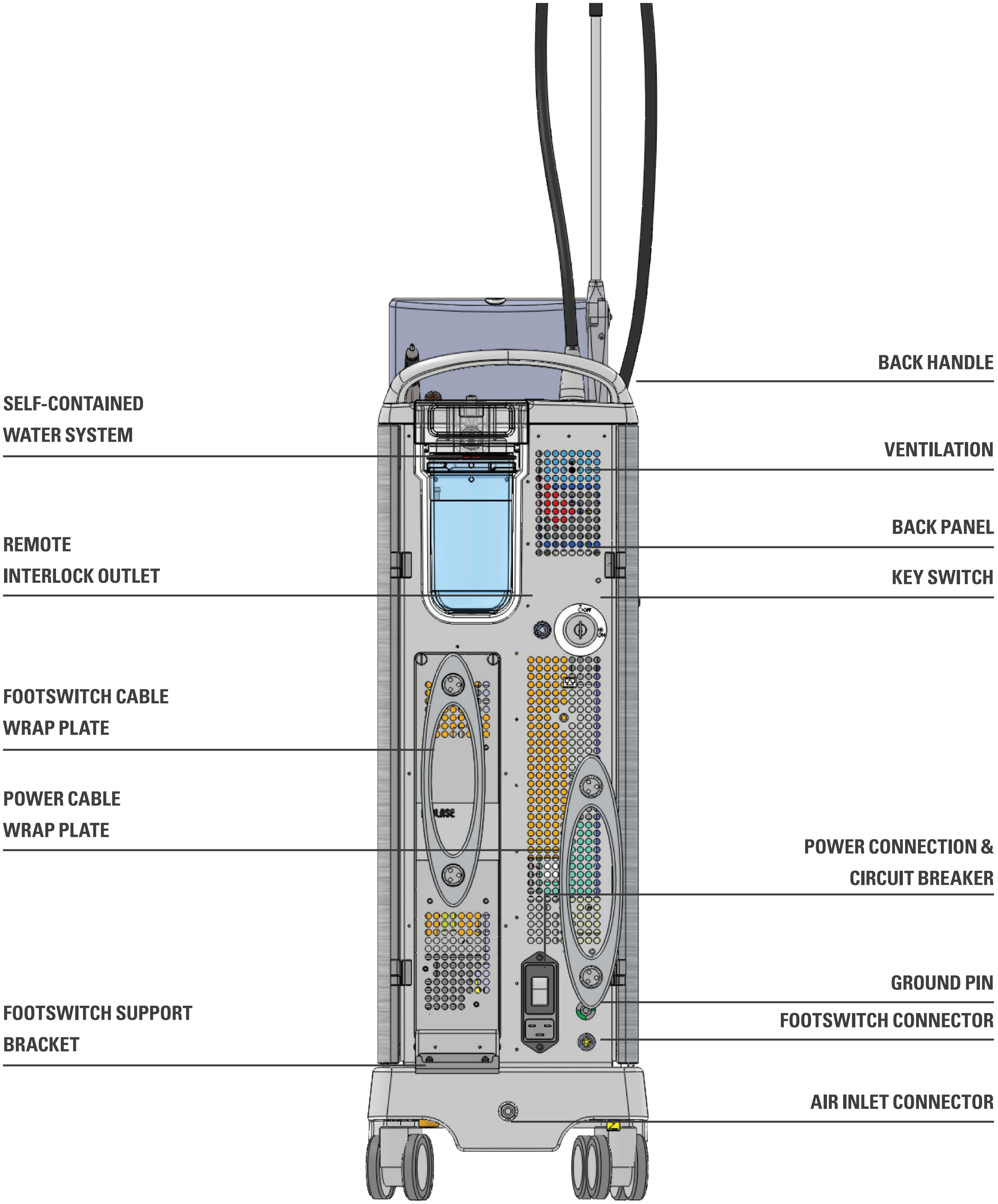

BACK HANDLE
SELF-CONTAINED WATER SYSTEM
VENTILATION
BACK PANEL
REMOTE INTERLOCK OUTLET
KEY SWITCH
FOOTSWITCH CABLE WRAP PLATE
POWER CABLE WRAP PLATE
POWER CONNECTION & CIRCUIT BREAKER
GROUND PIN
FOOTSWITCH SUPPORT BRACKET
FOOTSWITCH CONNECTOR
AIR INLET CONNECTOR

FIG 2.2

POWER CONNECTION / CIRCUIT BREAKER

Attach power cord to unit at this location. The circuit breaker serves as a line switch to separate the unit from the main power supply (0 = OFF, 1 = ON). Power cable can be wrapped over the holding plate above the connector when system is not in use or during transportation.

VENTILATION CHANNELS

Do not cover or block these channels. They provide an air flow path to cool the system.

AIR INLET CONNECTOR

Connect with tubing (included) to compressed dry air outlet at 80-120 psi (5.5 - 8.2 bar)

SELF CONTAINED WATER BOTTLE

Provides water supply for handpiece atomization spray. Fill bottle only with distilled or sterile water. **Do not use tap water.**

WATER BOTTLE RELEASE

When system is in “standby” mode, after bottle is depressurized, push the release button and pull back to remove the water bottle. After refilling the bottle, replace the bottle into its holder and secure the bottle in place.

FOOTSWITCH SUPPORT BRACKET

For storage or moving the unit, the bracket is designed to hold the closed footswitch clamshell. Wrap the footswitch cable around the wrap plate above.

FIBER SUPPORT ARM

Supports delivery system on the unit. It extends to support weight of the delivery system when handpiece is pulled forward. Extension comes back when handpiece is released and arm is in vertical position.

HANDPIECE HOLDER

Supports YSGG handpiece when not in use.

ILASE DIODE LASER

Sits in the charging cradle with additional charging port for spare battery.

NOTE: Proper placement of the Delivery System Cable in the Support Arm and of the Handpiece in the Handpiece holder is important for convenient and safe handling of the delivery system.

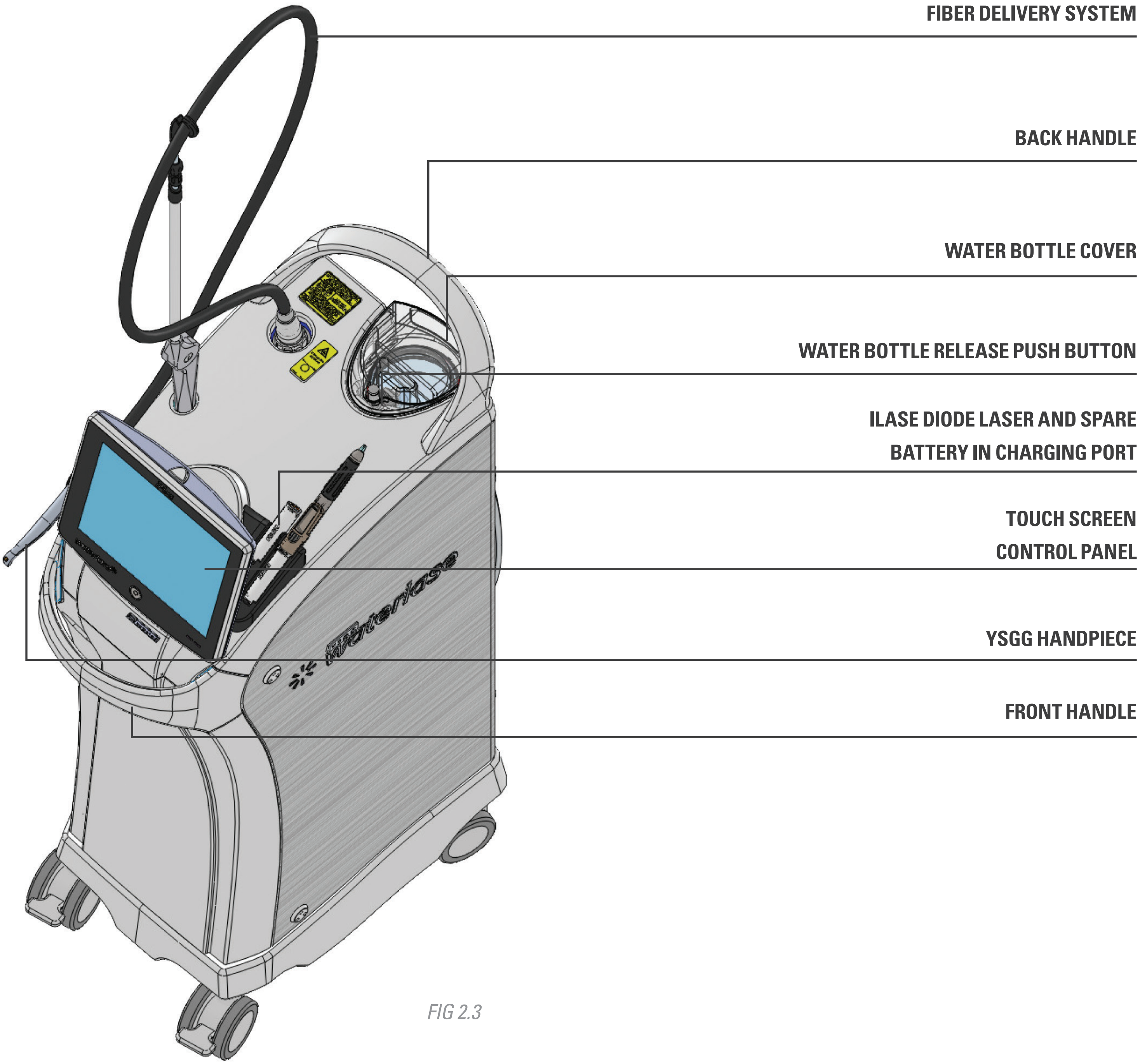

FIBER DELIVERY SYSTEM
BACK HANDLE
WATER BOTTLE COVER
WATER BOTTLE RELEASE PUSH BUTTON
ILASE DIODE LASER AND SPARE BATTERY IN CHARGING PORT
TOUCH SCREEN CONTROL PANEL
YSGG HANDPIECE
FRONT HANDLE
Waterlase

FIG 2.3

WATERLASE IPLUS DELIVERY SYSTEM

(see Section 4 for detailed description and instructions)

DELIVERY SYSTEM CONNECTION ON THE UNIT

The delivery system attaches to the unit via a multi-connector incorporating air, water, cooling air, illumination waveguides and the optical energy fiber optic.

FIBER OPTIC CABLE

Fiber optic cable contains the optical fiber together with the illumination waveguides, air tubing and water tubing. Laser radiation is delivered from laser unit to the handpiece through the optical fiber.

HANDPIECE

The YSGG handpiece is rotatable and detachable from the optical shaft. It delivers optical energy, illumination and atomized water spray to the treatment area.

ILASE CHARGING PORT

May hold one iLase laser handpiece and one extra iLase battery.

SETUP

CONNECT UNIT TO OPERATORY

1. Verify circuit breaker is in OFF position.

2. Verify keyswitch is in OFF position.

3. Connect power cord to unit (see fig.2.2).

4. Verify minimum air pressure of 80 psi (5.5 bar) from air supply.

5. Check air supply for moisture.

CAUTION: Do not connect the operatory air supply to the unit if water or oil is present. Air compressor may need to be drained or cleaned and air filters installed if moisture appears. Wet air will damage the unit. Check air supply weekly to verify absence of water and oil.

6. Connect to the unit's air inlet connector (see fig. 2.2).

FILLING THE INTERNAL COOLING WATER RESERVOIR

Your Waterlase iPlus may have been shipped with a full cooling water reservoir. In the event you need to fill the reservoir please follow the instructions below.

1. Open the back panel door by turning two thumb screws counter clockwise and pull back gently;

WARNING: Be careful opening the door. Make sure door opens easily and clears the bottle lid and tubing. Door holding bracket is mounted at the bottom hinge. Do not apply excessive force!

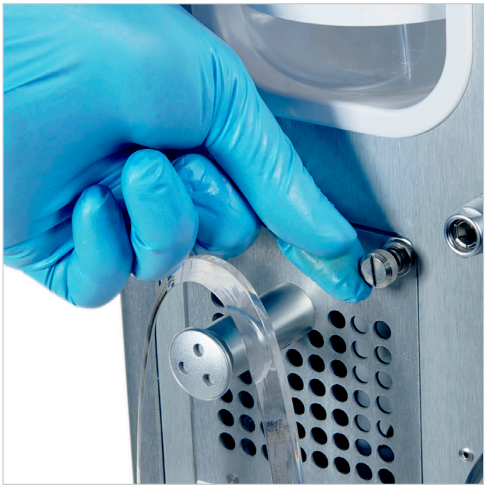


FIG 4.1

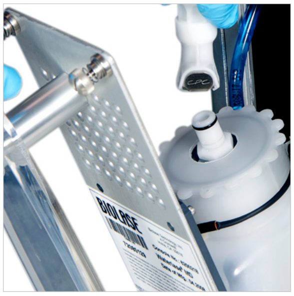


FIG 4.2

2. Locate internal water reservoir. Verify that white clip on the blue tube that is connected to the side of the water reservoir is closed;

3. Push button on the top connector and disconnect tubing from the lid;

4. Remove lid and filter assembly.

WARNING: Be careful handling the water filter assembly. Do not touch white filter material to prevent contamination and potential damage

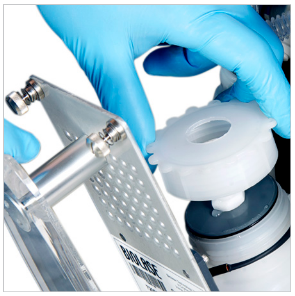


FIG 4.3

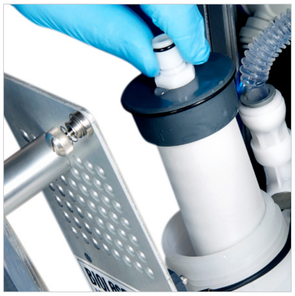


FIG 4.4

5. Use the funnel (supplied) to fill with distilled or deionized water to ¾'s full;

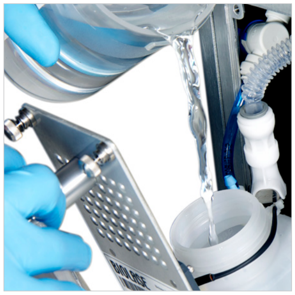


FIG 4.5

6. Replace filter assembly and close lid tight;

7. Plug in water connector firmly, until it “clicks” in place;

8. Power up the system:
- ➔ Switch the Power Circuit Breaker on the back panel ON;
- ➔ Turn the Keyswitch to the ON position;
- ➔ When keyswitch is turned ON, the system will begin its boot-up process. The system will load the software and the rotating tooth image appears on the display screen (about 30 seconds).

9. Press “Ready” key. If “Water level low” error message is shown, turn the system OFF refill the cooling water to ¾ full level.

10. Press “Ready” key again and let system run for 1-2 minutes to clear the air bubbles from all components of the cooling system.

11. Close the back door and tighten the two captive screws.

FILL SELF-CONTAINED WATER SYSTEM BOTTLE

1. Make sure that system is in the Standby mode (bottle is de-pressurized);

2. Push the bottle release button and pull the bottle out from the holder towards the back handle;

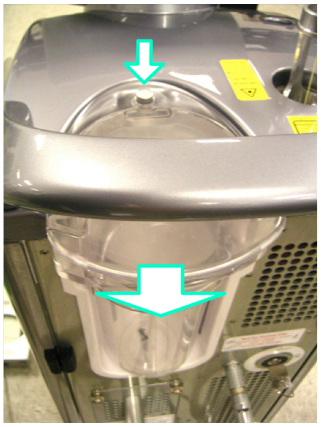


FIG 4.6

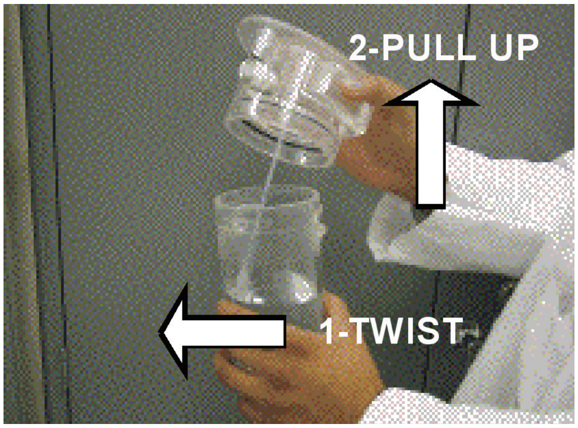


FIG 4.7

3. Twist the bottle clockwise and pull up the lid to open;

4. Fill bottle with distilled or sterile water only;

5. Align arrow on the lid and dot on the bottle and insert bottle into the lid;

WARNING: DO NOT use the tap water or non-authorized solution. If tap water or other non-approved solution is used, system warranty will be voided.

6. Twist the lid clockwise all the way until the arrows on both parts match;

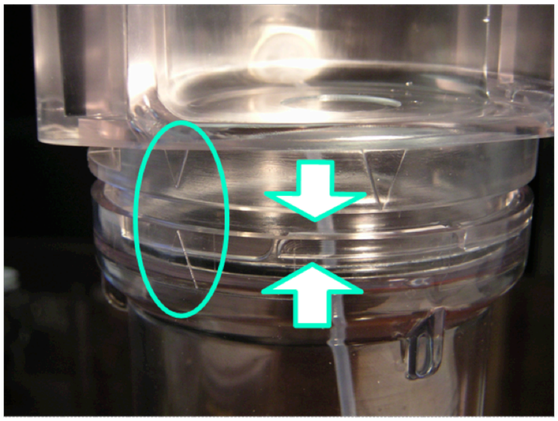


FIG 4.8

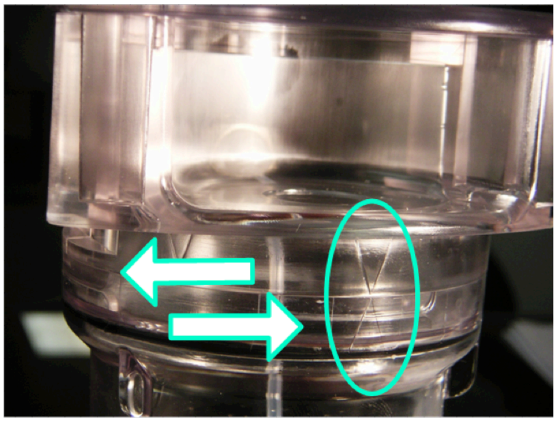


FIG 4.9

7. Attach bottle back to its holder; make sure connector is fully engaged.

WARNING: Be careful handling the water bottle assembly. Do not drop the parts. Any crack may cause damage when bottle is pressurized.

NOTE: BIOLASE recommends replacing the self-contained water system bottle once every five years.

SECURE FIBER OPTIC ASSEMBLY TO UNIT

1. Verify the Laser Head is centered to the top cover. If misaligned call Biolase headquarters for additional support;

2. Locate the hole on the left side of top view of laser unit and install telescopic fiber support arm;

3. Take the new trunk fiber from the accessories box and drape it around your neck;

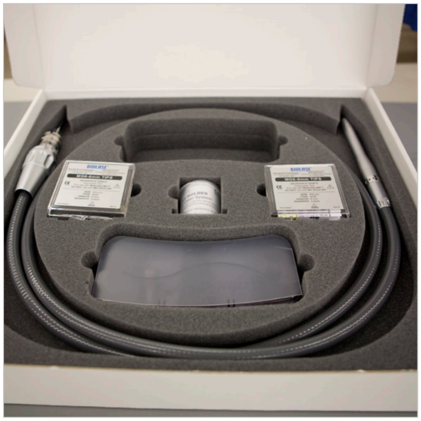


FIG 4.10

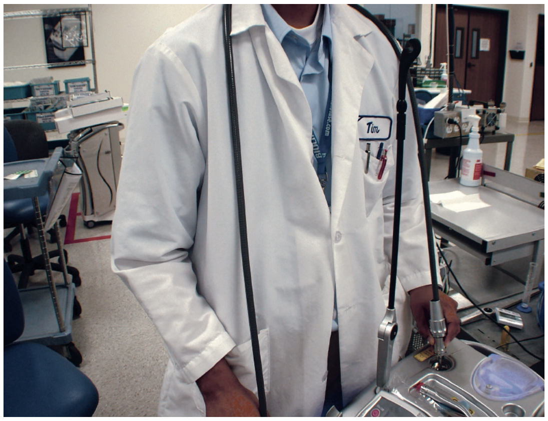


FIG 4.11

4. Remove protective black rubber cap at the proximal end of fiber;

5. Remove Protective Cover off the Fiber Shaft and place it against any light source. Check proximal end of the fiber – it should glow yellow, be flat and clean.

6. Remove black and red protective cups from laser head and aperture (store all the cups for further use,

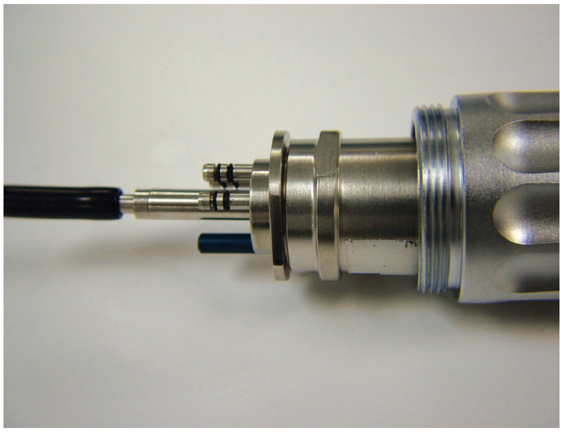


FIG 4.12

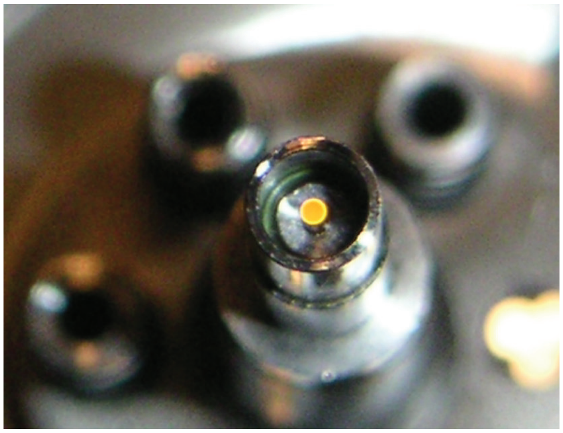


FIG 4.13

do not lose them);

7. Carefully look inside the laser aperture and check that surface of the protective window is clean, free of water, dirt or damage.

- If water or dirt found, try to clean by blowing the dry compressed air in the aperture;
- If this does not help – call for system Service.

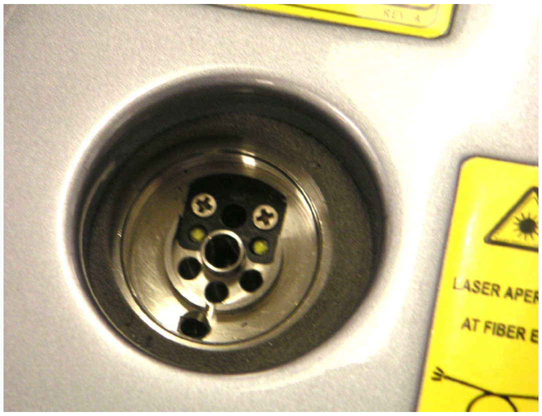


FIG 4.14

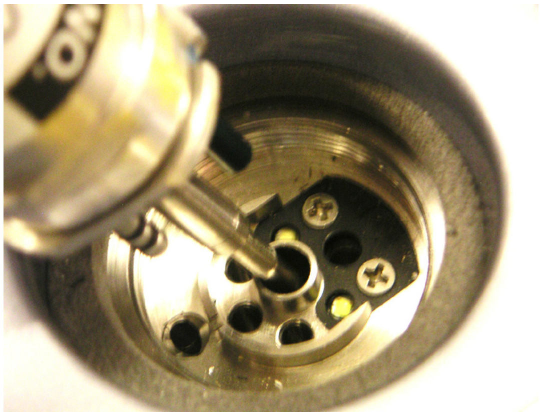


FIG 4.15

8. Align the blue guide of fiber connector to blue dot of laser head interface. Position the middle of the connector to the laser aperture and vertically push down gently all the way;

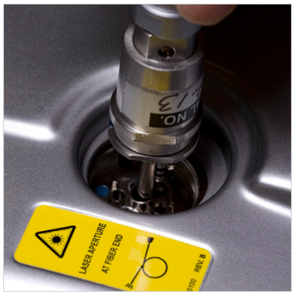


FIG 4.16

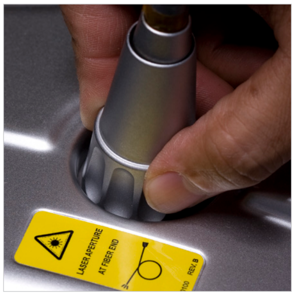


FIG 4.17

NOTE: You may need to move connector slightly to the sides to ensure proper engagement of all interfaces. DO NOT APPLY FORCE!

WARNING: Applying force may create metal shavings or shave off the o-rings of the spray connector and cause damage of the laser head components. .

9. Secure retainer ring by turning clockwise until it is snug;

10. Align middle of the fiber to the hook of telescopic arm and push gently to engage;

NOTE: Make sure the black retaining O-ring is in the front side of the hook.

11. Disconnect Protective Cover from the distal end of the Fiber Delivery Cable and verify that it is clean and not damaged (see also Maintenance Section);

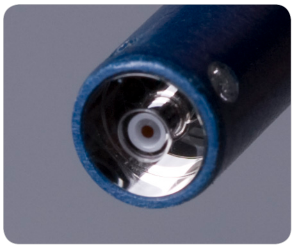


FIG 4.18

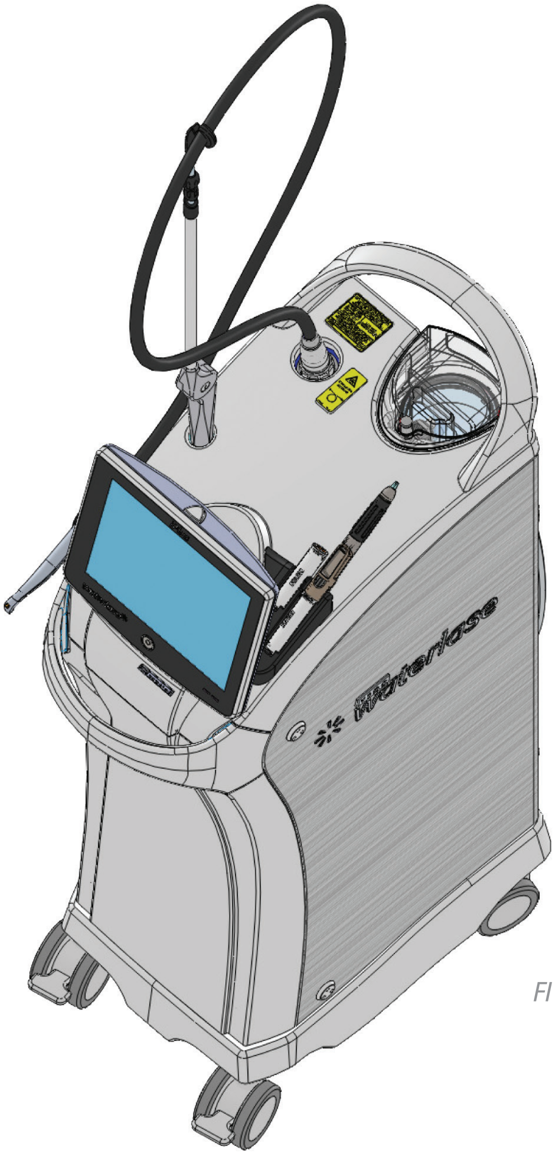


FIG 4.19

12. Properly align fiber and the Protective Cover (or the handpiece) in the handpiece holder.

CONNECTING YSGG HANDPIECE TO FIBER OPTIC CABLE

This procedure applies to the Gold and Turbo Handpieces.

1. Remove the Handpiece from the Handpiece Box;

2. Remove the Rear Plug from the handpiece by pulling the plug out and place it in the Handpiece Box to store;

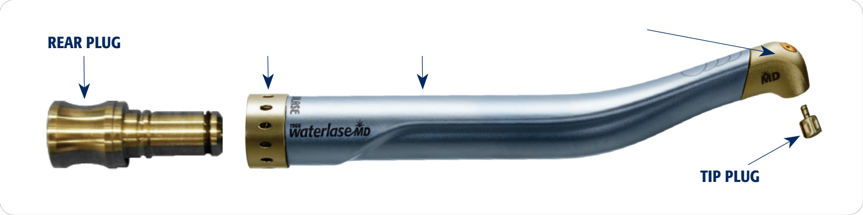


FIG 4.20

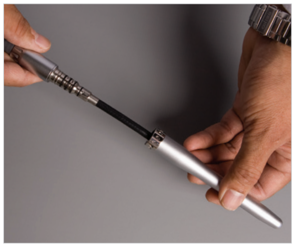


FIG 4.21

3. Remove the fiber Protective Cover from the Fiber Shaft of the Trunk Fiber by pulling the cover off and place it in the Handpiece Box;

4. Check the Fiber Shaft for any moisture and wipe off any that is found;

NOTE: Check output end of the Fiber Shaft for any contamination of damage (see Maintenance Section)

WARNING: Do not touch output end of the Fiber Shaft to prevent any contamination and potential further damage. If touched, clean with dry tissue.

5. Carefully insert the Fiber Shaft into the Handpiece until it "clicks".

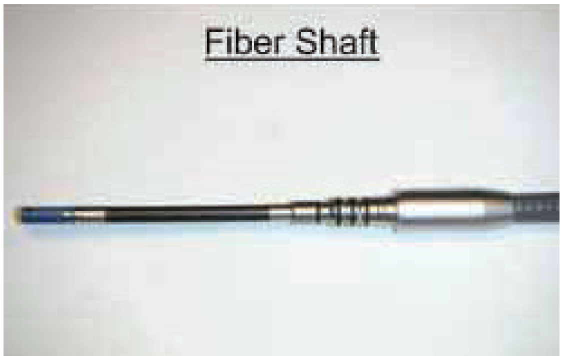


FIG 4.22

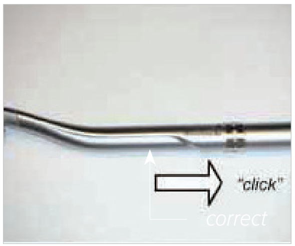


FIG 4.23

NOTE: Connection and disconnection of the Handpiece and the Protective Cover should be done carefully, without application of excessive force.

WARNING: To prevent the internal fiber from braking, do not bend the flexible part of the Fiber Shaft.

DISCONNECTING THE HANDPIECE

1. Purge the handpiece by following the instructions described in how to change a handpiece in the Graphical User Interface (GUI), Section 5;

2. Pull and disconnect the Handpiece from the Fiber Shaft;

WARNING: Failure to purge the handpiece prior to disconnecting may cause damage of the Fiber Delivery system.

3. Wipe any moisture off the Fiber Shaft with dry tissue;

4. Check that window at the end of the fiber is clean (use dry cotton swab or tissue to clean) and not damaged (see also Maintenance Section);

5. Carefully attach new Handpiece or fiber Protective Sheath until it “clicks” on the Fiber Shaft;

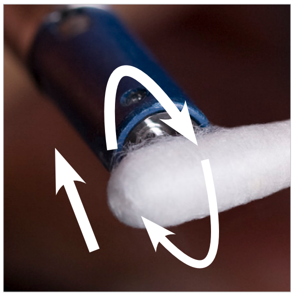


FIG 4.24

WARNING: Do not press ”Done” button if fiber Protective Cover is attached – water will fill the Cover and may cause damage of the Fiber Shaft. If this happens, take the Cover off and dry out both Fiber Shaft and Protective Cover. Failure to do so may result in damage to the Fiber Shaft.

INSTALLING AND CHANGING TIP IN THE HANDPIECE

This procedure applies to the Gold and Turbo Handpieces.

1. Set the system in the “Standby” mode;

2. Set the system in Advanced mode (Fig 5.11). Press tip change button at bottom.

> **NOTE**: Always change Tips after pressing the tip change button to turn on patient air and cooling air. This helps clean the input end of the tip from any light dirt or moisture.

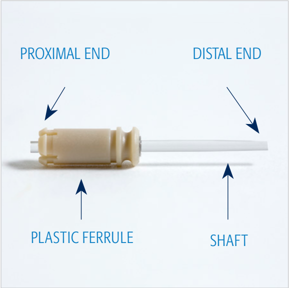


FIG 4.25

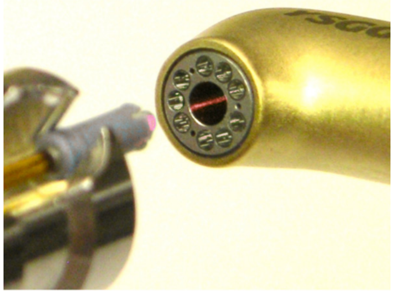


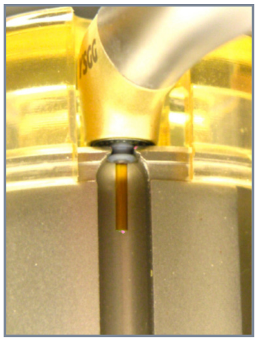
FIG 4.26

3. Remove the Tip Plug by pulling it out and place it in the Handpiece Box;

4. Remove Tip from the package (for new Tips only) and insert it into the Tip Remover or revolving Tip Holder. Insert by aligning the first groove of the Tip Ferrule against the receiving edges of the Holder, then sliding the Tip in (the use of tweezers is highly recommended);

> **WARNING:** Never touch the input end of the Tip. If the input surface is contaminated, it may damage the Tip, Handpiece and the Fiber Delivery System. Hold the tip only over the plastic ferrule and the output end.

> **NOTE**: Always inspect the Tip prior to use (See Sec. Tip Inspection).



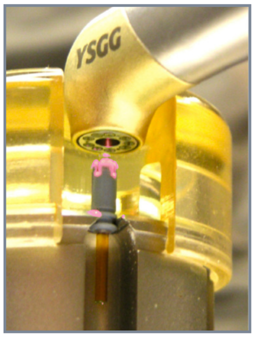


FIG 4.28

5. Align the tip orifice of the handpiece over the input end of the Tip, placed in the Tip Remover or revolving Tip Holder;

6. Carefully lower the handpiece and insert a clean/inspected Tip (see: Tip Inspection) all the way until the shoulder of the tip ferrule sits against the handpiece head;

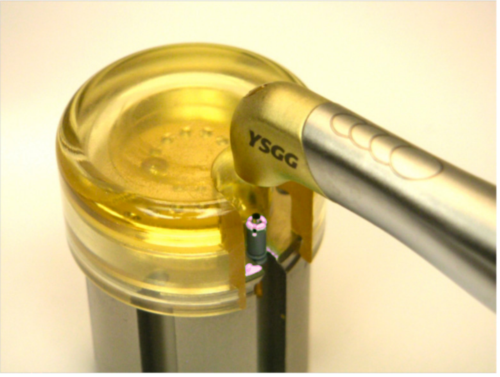


FIG 4.29

WARNING: Be careful not to hit the proximal end of the Tip against the handpiece head and not to break retaining fingers of the plastic ferrule.

7. Slide the Handpiece laterally away from Tip Remover or Tip Holder.

8. Press the tip change button again on the advanced screen to stop patient air and cooling air.

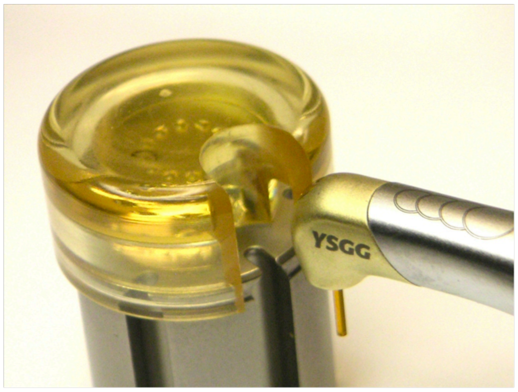


FIG 4.30

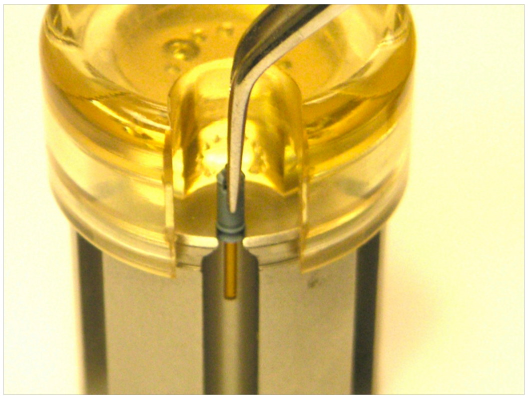


FIG 4.31

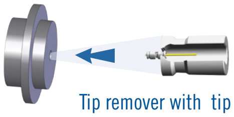
NOTE: To remove the Tip, repeat the whole process in reverse order. Put your thumb against the selected tip slot to prevent Tips from falling out of the Tip Holder when connecting and disconnecting Tips from the Handpiece.

NOTE: If the laser cuts hard and soft tissue after fiber installation slower than expected, please follow the flowchart in Sec. Troubleshooting the Delivery System.

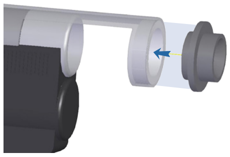
NOTE: Use same techniques when operating MD Turbo handpiece and MX Tips. Also note that (1) the Turbo tip holder/remover tool is different than the regular tip holder/remover; (2) the Turbo tool works ONLY with Turbo tips; and (3) the regular tool does NOT work with Turbo tips. Also refer to the Turbo Handpiece instructions for use for more information, P/N 5200147.

TIP INSPECTION INSTRUCTIONS

[01] Remove the tip from the handpiece and insert it into the correct side of the tip test holder as shown using the tip remover.

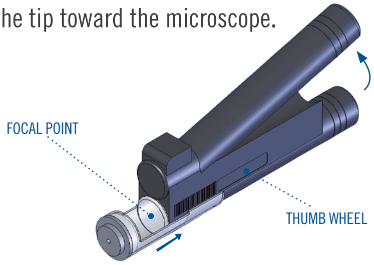


Tip remover with tip inside

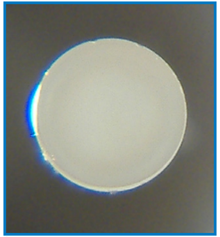


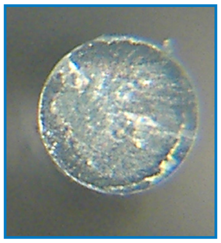
[02] Insert the tip test holder into the test adapter with the distal (or laser-emitting) end of the tip toward the microscope.

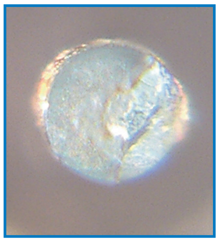
[03] Slide the adapter over the microscope to move the tip surface toward the focal point of the microscope. The focal point lies in the plane at the end of the clear end tube of the microscope.

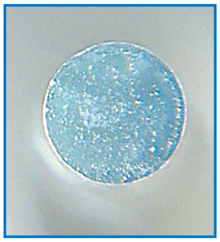


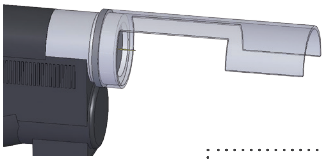
[04] Turn on the microscope's built-in light by gently pulling apart the upper and lower tubes, or hold it up to another light source, and bring the surface of the tip into focus using the thumb wheel. Examine the tip surface carefully for damage or contamination.

✓

GOOD

⊘

BURNT

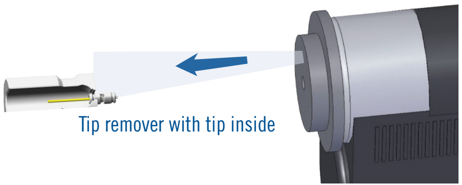
⊘

BROKEN

⊘

CONTAMINATED



[05] To examine the proximal (or trunk fiber) end of the tip, remove the adapter from the microscope, and gently fit the other side of the test holder into the clear end tube of the microscope. Refocus the Microscope.

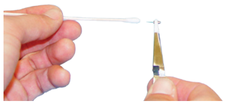
[06] Remove the tip from the test holder using the tip remover. If the tip is contaminated at either end, try cleaning it as shown below. If the tip is damaged, replace it from the handpiece using the tip remover and dispose of it.



Tip remover with tip inside

TO REPLACE THE BATTERIES FOR THE BUILT-IN MICROSCOPE LIGHT, gently pull apart the upper and lower tubes of the microscope. Locate the battery cover marked with "OPEN", slide the cover in the direction of the arrow, remove the old batteries and replace with two size AA 1.5 volt (Europe size M) batteries.

TIP CLEANING INSTRUCTIONS



1. Hold tip with tweezers.
2. Moisten cotton swab with 100% isopropyl alcohol drops
3. Push tip into cotton swab
4. Twirl cotton swab while maintaining pressure on tip

5 Operating Instructions

OPERATION

CAUTION: Use of controls or adjustments and performance of procedures other than those specified herein may result in hazardous radiation exposure.

OVERVIEW

Before using the Waterlase iPlus, be sure the system has been started appropriately, as described earlier in this manual.

5 Operating Instructions

(continued)

TO START THE WATERLASE IPLUS

1. Verify that all connections have been properly secured and fiber cable properly attached

2. The Air supply must be connected and the external air pressure must be at 80 PSI (5.5 bar) or more.

3. Electrical input should be at least 100 VAC, maximum 15 amperes to 230VAC, 8 amperes.

4. Verify that the water bottle is more than 1/3 filled with distilled or sterile water.

DANGER: Laser and collateral radiation are emitted through the fiber optic port. Removal of the multiconnector from the fiber optic port may lead to hazardous exposure. Radiation is also emitted from the fiber shaft when the handpiece is removed. DO NOT attempt to operate the Waterlase iPlus with the delivery system or the handpiece not attached.

5. Switch the circuit breaker ON.

6. Insert the key into the keyswitch and rotate clockwise to the ON position.

7. The emergency stop button must be released (verify by making sure the button is not glowing red, and no error message is displayed).

8. The system will begin its startup process. The system will load the software and the tooth image appears on the display screen (about 30 seconds).

9. Attach handpiece to the fiber optic cable shaft (Sec. 4: Connecting the Handpiece to Fiber Optic Cable).

10. Place system into Standby mode and attach tip using the tip remover (Sec. 4: Installing and Changing Tip Into Handpiece)

ACTIVATE THE WATERLASE IPLUS

Push the Ready button to enable the Waterlase iPlus, and depress the footswitch when ready.

NOTE: The user may evaluate the effect of each parameter setting prior to the procedure directing the handpiece into a sink or paper cup and adjusting the values as desired

NOTE: To help prevent inadvertent laser activation, there is a 0.5-second delay between footswitch depress and actual laser emission.

TURN THE WATERLASE IPLUS OFF

- Disconnect tip, if required. Install tip plug.
- Press and hold the function control button for 2 seconds to turn the system OFF.
- Turn key to OFF position
- Turn circuit breaker to OFF.

USER INTERFACE / GENERAL NAVIGATION

INTRODUCTION

The Graphical User Interface (GUI) is the main part of the system control, communicating to the user through the interactive touch screen display. It is designed to provide easy and intuitive interaction with the laser system during performance of clinical procedures.

The system automatically selects recommended pre-programmed settings correspondent to the selected clinical application. It minimizes potential error of setting laser parameters and creates a more satisfactory experience for both user and patient.

CONTROLS AND INDICATORS.

The control panel (Fig. 5.1) has one functions control button for turning the system ON and OFF, and for switching between Standby and Ready Modes. Pressing and holding the button for more than 2 seconds will turn the system ON / OFF. When ON, pushing the button will switch the system between Standby and Ready Modes.

The control panel also has one LED indicator for system status and laser power actuation. An amber light indicates that the system is in Standby Mode. A green light indicates Ready Mode, and a blinking green indicates that the laser is firing.

There are also two status indicators for the iLase batteries: Amber light for charging mode, Green light for fully charged state.

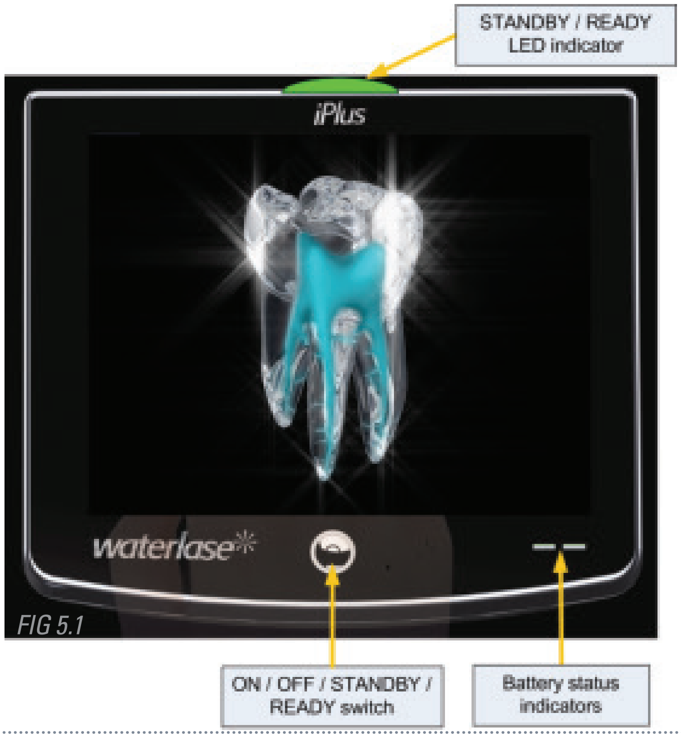

STANDBY / READY LED indicator
iPlus
waterlase
ON / OFF / STANDBY / READY switch
Battery status indicators

FIG 5.1

APPLICATIONS MENU

LEVEL 0 DESCRIPTION

After the system is powered up, there is approximately 45 second delay for loading the software. After the system is loaded, a tooth is displayed on the screen like a screen saver. A touch of the screen will bring the system to Level 0 Home Menu (See Fig. 5.2 and Flow Chart in Fig. 5.15) and one can see the tooth tissues with option to select the operational areas.

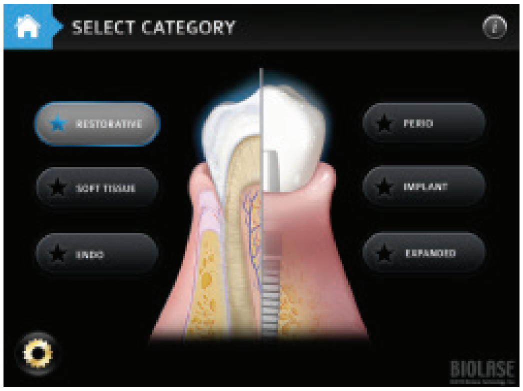

SELECT CATEGORY
RESTORATIVE
SOFT TISSUE
ENDO
PERIO
IMPLANT
EXPANDED
BIOLASE

FIG 5.2

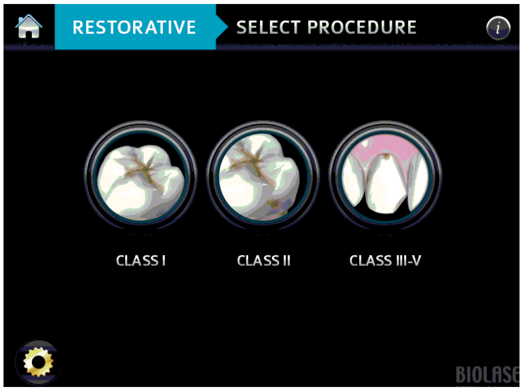

RESTORATIVE
SELECT PROCEDURE
CLASS I
CLASS II
CLASS III-V
BIOLASE

FIG 5.3

There are **6 main categories** of procedures to be selected at this level:

- Restorative
- Periodontics
- Endodontics
- Soft Tissue
- Implantology
- Expanded

To select the procedure category press the name on the touch screen.

The system is in Standby Mode and cannot be turned to Ready Mode while the Home Menu is displayed.

LEVEL 1 DESCRIPTION

When a procedure category is selected, the system goes to Level 1 with a number of clinical applications within the selected category, which have been tested to be efficient for use with Waterlase technology (See Fig. 5.3 as example).

Currently there are 16 procedures completely identified within 6 Procedure Categories (See the Flow Chart, Fig. 5.15).

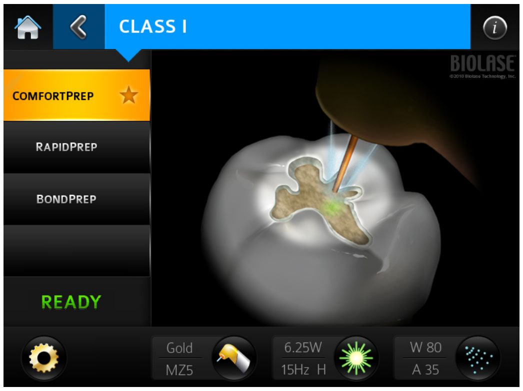


FIG 5.4

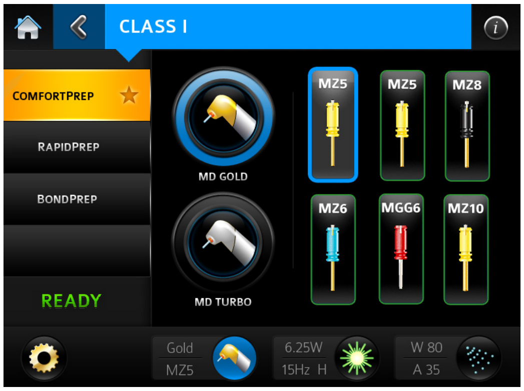


FIG 5.5

To select a procedure – touch the correspondent name or image.

The system is in Standby Mode and cannot be turned to Ready Mode.

LEVEL 2 DESCRIPTION

When a particular procedure is selected, the system goes to Level 2 (See Fig. 5.4 for an example). At this level, all laser operating parameters are identified as pre-sets for the selected step within the procedure. Several steps to follow during the procedure are recommended.

Each step has its own name (which may be also a trademark name). Each step has its own recommended settings.

Changing Water in the bottle. When water in the bottle is detected LOW, a blinking button with a low water level symbol will appear next to the Settings button. The user may then place the system into Standby Mode to allow the user to change the water in the bottle. When the bottle is disconnected, an Error screen will appear. When the bottle is re-attached, the Error screen shall be cleared either automatically, when the bottle status is checked by the system, or manually. Pressing the main Function button (below the touchscreen) will return the system to Ready Mode. The same algorithm is true for all procedure screens.

Three setting categories are shown at the bottom: Handpiece and Tip, Laser, and Spray. Adjustments can be made to:

- Handpiece type and Tip type: all tips which are allowed for this procedure
- Laser: Power, Pulse Repetition Rate and Pulse Mode
- Spray: Water and Air percentage

Handpiece type is selected as preferred for the current procedure step and is named at the bottom.

Handpiece can be changed to the same type or a different type. **To do so**

1. First, press the handpiece image button; the system shall automatically purge the water from the handpiece (Patient Air 100% ON, air pressure in the bottle OFF, Patient Water 100% ON); a progress timer will be shown (3-4 second) in a form of a segmented circle outside of the handpiece icon in the button, and water will be purged from the handpiece;

2. When done, a new message: "Excnge Handpiece now and then select Tip" shall appear. At that time a new handpiece can be re-attached.

(continued)

3. Then press the desired tip image (which might be the same tip or a new tip); patient air (and internal cooling air) will be activated through the handpiece, and a new tip may be inserted.
4. After a new tip is attached to the new Handpiece, press the handpiece image again; a progress timer is shown again for 3-4 second, and the handpiece shall be primed with water.

To come back to the Procedure screen, the back or handpiece button at the bottom row should be pressed again.

TIPS selection always corresponds with the selected handpiece type. Their names are shown at the bottom of each tip image for reference. When the Tip Selection is active, one main recommended tip is highlighted, preferred tips are outlined, and all allowed-for-use tips are shown (Fig. 5.6).

- ➔ Press the tip image (which might be the same tip or a new tip);
- ➔ Both Cooling Air and Patient (spray) Air will turn ON;
- ➔ Replace the tip.

To come back to the Procedure screen when the tip is installed, the back or handpiece button at the bottom row should be pressed again.

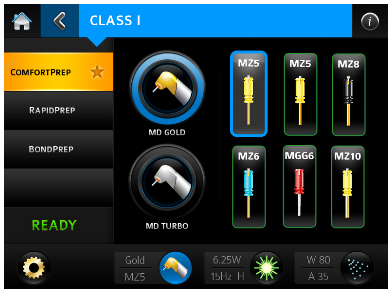
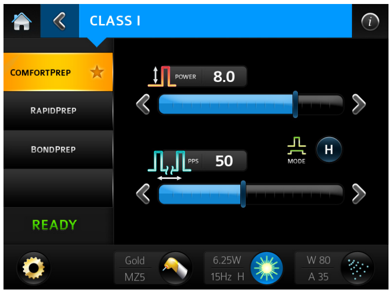

CLASS I
COMFORTPREP
RAPIDPREP
BONDPREP
READY
MD GOLD
MD TURBO
MZ5
MZ5
MZ8
MZ6
MGG6
MZ10
Gold
MZ5
6.25W
15Hz H
W 80
A 35

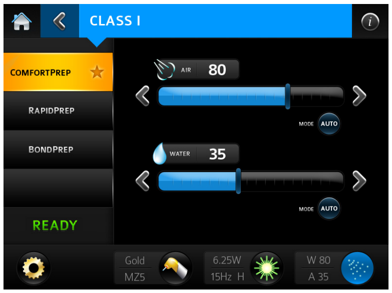
FIG 5.6


CLASS I
COMFORTPREP
RAPIDPREP
BONDPREP
READY
MODE
H
Gold
MZ5
6.25W
15Hz H
W 80
A 35

POWER 8.0

PPS 50

FIG 5.7


CLASS I
COMFORTPREP
RAPIDPREP
BONDPREP
READY
MODE AUTO
MODE AUTO
Gold
MZ5
6.25W
15Hz H
W 80
A 35

AIR 80

WATER 35

FIG 5.8

LASER power setting as well as pulse prepetition rate and laser pulse mode are always defined by the type of procedure and the selected tip type (Fig 5.7). The Pulse Mode button switches the system between S (long pulse) and H (short pulse) modes. Laser parameters can be changed at any time in Ready or Standby Modes. After adjustment, pressing the back or Laser button will bring the system back to the Procedure screen.

SPRAY settings for air and water % can also be adjusted in Ready or Standby Modes (Fig 5.8).
Mode selection scrolls between ON, OFF and AUTO for both parameters.

CHANGING AND SAVING THE PRE-SETS

When system parameters are changed from factory pre-sets, the “star” symbol changes to an “unlocked lock” symbol. That indicates that the system pre-set parameters have been modified but not saved.

To save modified parameters, press and hold the step name’s button for 2 seconds. The “unlocked lock” symbol shall change to a “locked lock” symbol, indicating that the modified settings have been saved. Otherwise, the modifications will be lost when going to a different screen.

To restore factory pre-programmed settings for the customized procedure step (indicated by a “locked lock” symbol), the correspondent step name’s button shall be pressed and held for 2 seconds. The “star” symbol shall re-appear in place of the “locked lock” symbol, indicating that settings have been changed back to factory pre-set values.

Factory recommended or modified settings can be saved as one of the “Favorites”, if required.
The entire original factory pre-sets can be restored as well, when in the Settings Menu “RESTORE ALL” icon is selected.

None of the parameters can be changed when system is in FIRING mode.

De-fault settings for Illumination (both Aiming Beam and Light) are in the middle of the adjustment range. The same is true for the Sound Tone.

SETTINGS / MEMORY MENU

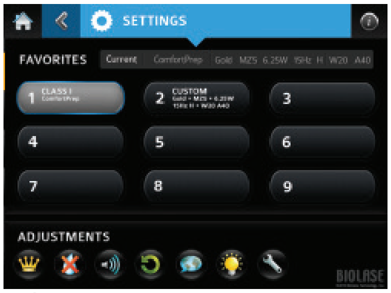
The Settings / Memory Menu stores up to 9 “Favorites” (Fig. 5.9). It can correspond to a particular step of the procedure described in the Main Application Menu or can be completely independent, if selected by the user and stored from the Advanced Menu.

This Menu also provides access to the following supplementary functions:

- Access to the Custom operational menu, Advanced Menu, not associated with any clinical procedure;
- Purging and priming of the fiber delivery system;
- Adjustment of the loudness of the touch-tone;
- Restoration of all factory pre-sets;
- Selection of the Language;
- Adjustment of the Aiming beam and Illumination;
- Access to the Service Screen.

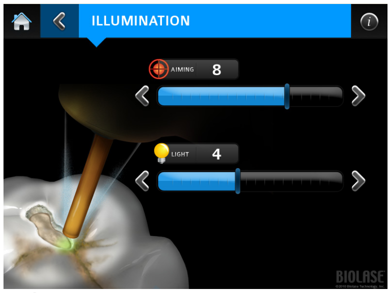
When switched to this screen from the Procedure screen or from the Advanced screen, the latest settings and name of the procedure step are displayed in the top row. To save the current settings into one of the "Favorites", press and hold one of the nine buttons for 2 seconds. The name of the procedure and step will appear within the button. When working from the Advanced screen, the name for the button will be given as "Custom 1", etc.

FUNCTIONS FOR THE SETTING BUTTONS



Current ComfortPrep Gold MZ5 6.25W 15Hz H W20 A40

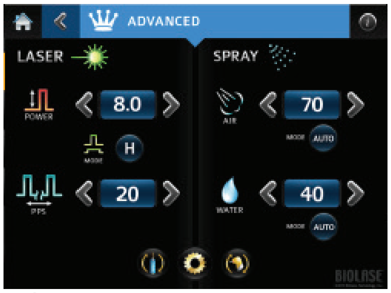
FIG 5.9



AIMING 8

LIGHT 4

FIG 5.10



POWER 8.0

MODE H

PPS 20

AIR 70

MODE AUTO

WATER 40

MODE AUTO

FIG 5.11

- **ADVANCED** button switches the system to the Advanced mode;
- **DRAIN WATER** button shall be used only when replacing the fiber. When pressed, "Purge" and "Prime" buttons appear. When "Purge" is activated – the fiber shall be purged of water.

When "Prime" is activated – the fiber shall be primed with water.

- **SOUND** will lead to adjustment of sounds within the range 0 to 15.
- **RESTORE** function will lead to dialogue screen "Do you want to restore all factory pre-sets?" with YES and Exit options. If YES is selected, all factory pre-sets will be restored.
- **LANGUAGE** button gives an option of selecting one of multiple languages.
- **ILLUMINATION** screen will have adjustments for visible aiming beam and light illumination for Handpiece from 0 to 9.
- **SERVICE** button will lead to Service Menu.

CUSTOM SETTINGS

The user has the capability to adjust parameters without any limitation and without relation to any procedure in the Advanced screen (Fig. 5.11).

When selecting the "Advanced" button, the system goes to the screen with all parameters shown, without referencing any particular procedure or limiting any range of adjustments.

POWER LIMITS FOR THE SYSTEM ARE SHOWN IN THIS TABLE:

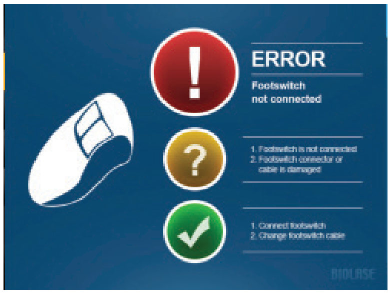
Pulse rate, Hz	*H - mode*		*S - mode*	
	Min power, W	*Max Power, W*	*Min power, W*	*Max Power, W*
5	*0.10*	*2.50*	*0.10*	*2.50*
8	*0.10*	*4.75*	*0.10*	*4.75*
10	*0.10*	*6.00*	*0.10*	*6.00*
12	*0.10*	*7.25*	*0.10*	*7.25*
15	*0.10*	*9.00*	*0.10*	*9.00*
20	*0.10*	*10.00*	*0.10*	*10.00*
25	*0.25*	*10.00*	*0.25*	*10.00*
30	*0.25*	*10.00*	*0.25*	*9.00*
40	*0.25*	*9.00*	*0.25*	*8.00*
50	*0.25*	*8.00*	*0.25*	*6.00*
75	*0.50*	*6.00*	*0.00*	*0.00*
100	*0.50*	*4.00*	*0.00*	*0.00*

These parameters are for all MX, MC tips and MZ10, MZ8, MZ6 and MS75 tips.

DESCRIPTION OF FUNCTIONAL BUTTONS:

- **Change Handpiece** selection will automatically purge the water from the handpiece, with a progress timer displayed (3-4 second). Then a message to change the handpiece will appear. When the handpiece is changed, the same button should be pressed and the priming cycle starts with progress segmented circle shown.
- **Change Tip** selection turns both Internal Cooling air and Patient air ON. When pressed again, the system will return to the Advanced screen.

SETTINGS button leads to the Settings screen.



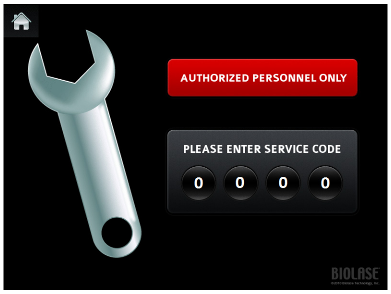
ERROR

Footswitch not connected

1. Footswitch is not connected
2. Footswitch connector or cable is damaged

1. Connect footswitch
2. Change footswitch cable

FIG 5.12



AUTHORIZED PERSONNEL ONLY

PLEASE ENTER SERVICE CODE

0 0 0 0

FIG 5.13

OTHER SCREENS

Help "i" icon on icon on every screen can be selected to go to an Information / Recommendations Screen.

Error screen screen will appear when a system error is detected. It will give the Error name and recommendations for how to correct it (Fig 5.12).

Service screen screen will have a pass code to provide access to authorized personnel (Fig. 5.13).

SYSTEM FLOW CHART:

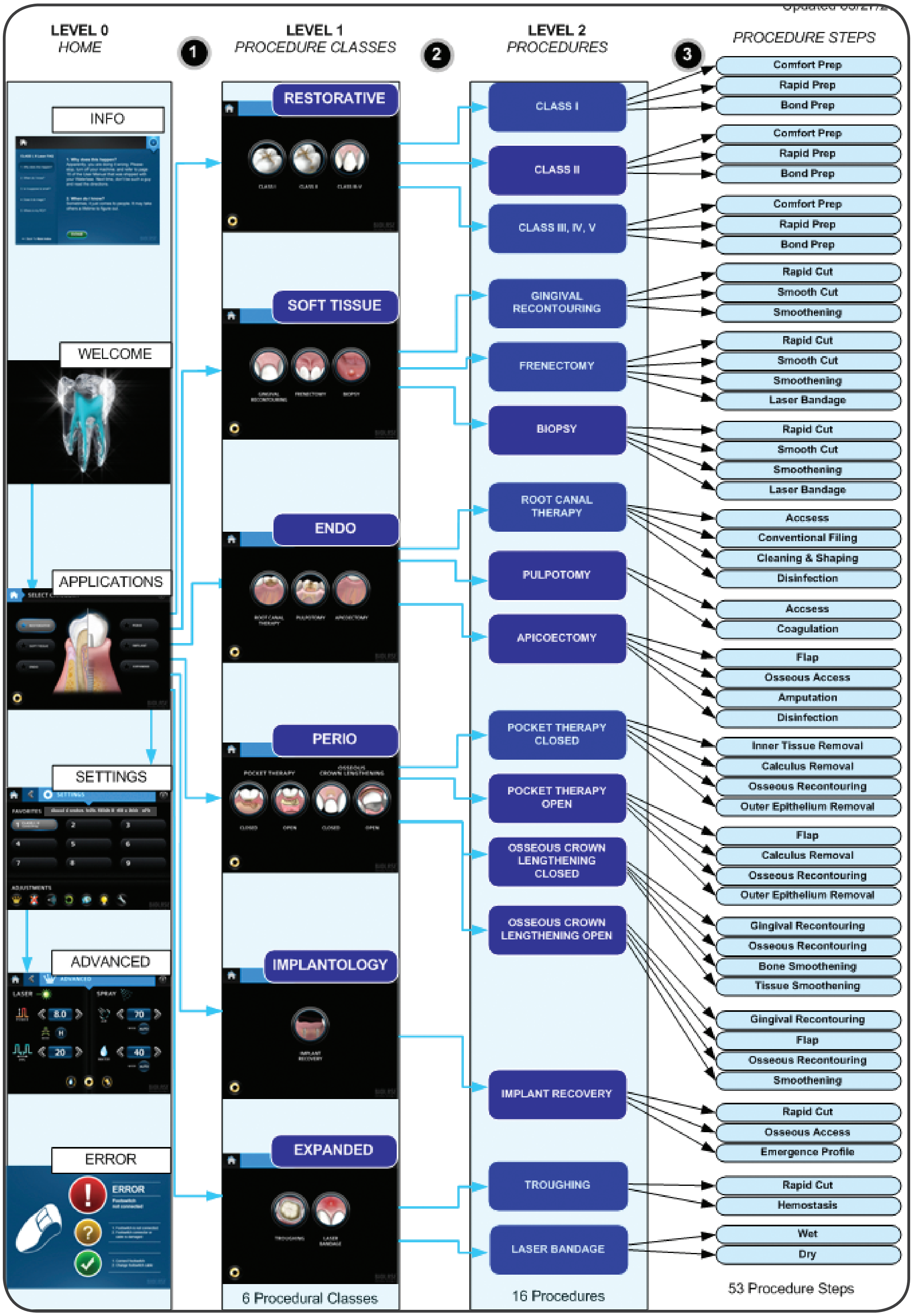

LEVEL 0
HOME
INFO
WELCOME
APPLICATIONS
SETTINGS
ADVANCED
ERROR
1
LEVEL 1
PROCEDURE CLASSES
RESTORATIVE
SOFT TISSUE
ENDO
PERIO
IMPLANTOLOGY
EXPANDED
6 Procedural Classes
2
LEVEL 2
PROCEDURES
CLASS I
CLASS II
CLASS III, IV, V
GINGIVAL RECONTOURING
FRENECTOMY
BIOPSY
ROOT CANAL THERAPY
PULPOTOMY
APICOECTOMY
POCKET THERAPY CLOSED
POCKET THERAPY OPEN
OSSEOUS CROWN LENGTHENING CLOSED
OSSEOUS CROWN LENGTHENING OPEN
IMPLANT RECOVERY
TROUGHING
LASER BANDAGE
16 Procedures
3
PROCEDURE STEPS
Comfort Prep
Rapid Prep
Bond Prep
Comfort Prep
Rapid Prep
Bond Prep
Comfort Prep
Rapid Prep
Bond Prep
Rapid Cut
Smooth Cut
Smoothening
Rapid Cut
Smooth Cut
Smoothening
Laser Bandage
Rapid Cut
Smooth Cut
Smoothening
Laser Bandage
Accsess
Conventional Filing
Cleaning & Shaping
Disinfection
Accsess
Coagulation
Flap
Osseous Access
Amputation
Disinfection
Inner Tissue Removal
Calculus Removal
Osseous Recontouring
Outer Epithelium Removal
Flap
Calculus Removal
Osseous Recontouring
Outer Epithelium Removal
Gingival Recontouring
Osseous Recontouring
Bone Smoothening
Tissue Smoothening
Gingival Recontouring
Flap
Osseous Recontouring
Smoothening
Rapid Cut
Osseous Access
Emergence Profile
Rapid Cut
Hemostasis
Wet
Dry
53 Procedure Steps

FIG 5.15

ERROR MESSAGES

The Waterlase iPlus constantly monitors its own performance and calibration. If any performance errors occur, the system will be placed in Standby mode and the screen will indicate the cause of the error and provide recommendations on clearing the error.

If you cannot clear an error after following the directions on the error screen, please call your local service representative for assistance.

Error Number	Error	Reason	Fix	Corrective Action
6	All bottle sensors off	Possible error in light source	Check bottle sensor light source	Check bottle straw, clean sensors
7	Bottle sensor 1 off, 2 on	Possible defective sensor 1	Check Bottle sensor	Check bottle straw, clean sensors
8	All bottle sensors on	Error in bottle sensor system	Check out bottle sensor system	Check bottle straw, clean sensors
13	Foot Switch pressed in Standby Mode	Foot Switch pressed in Standby Mode	Release the Foot Switch	Check connector, Switch to “Ready” mode
15, 28	Interlock is open	Interlock is open	Check Interlock	Check Remote Interlock connector at back panel
17	Shut Down temperature condition	System Temperature is high	Allow system to cool down	Let system run in “Ready” mode for 5-10 minutes
18	Emergency switch pressed	Emergency switch pressed	Check Emergency switch	Release the Emergency Stop Button at the front
19	No bottle error	Bottle not detected	Insert bottle or repair sensor	Insert water Bottle and clean the sensors
23	Reservoir fail	Cooling water level is low	Add de-ionized/distilled water	Add specified water, if trained on that
24	Air pressure failure	Air pressure failure	Check air compressor	Air pressure might be low or disconnected
26	Foot Switch not detected	Foot Switch not connected	Connect Foot Switch	Check connector, footswitch short during standby
29	Fiber not detected	Fiber not detected	Check Fiber	Properly re-connect the Trunk Fiber
31	No water	No water in bottle	Add water to bottle	Add water to bottle

6 Specifications

GENERAL

DIMENSIONS (W X L X H)

- Unit 11 x 19 x 33 in (28 x 48 x 84cm)
- With Fiber 11 x 19 x 40 in (28 x 48 x 102 cm)
- Weight 75 lbs (34 kg)

ELECTRICAL

- Operating Voltage: 100 VAC ± 10% / 230VAC ± 10%
- Frequency: 50 / 60 Hz
- Current rating: 15.0 A / 8A
- Main control: Circuit breaker
- On / Off control: Keyswitch
- Remote interruption: Remote interlock connector

WATER SPRAY

- Water type: Distilled or Sterile
- External air source: 80 - 120 psi. (5.5 - 8.2 bar)
- Water: 0 - 100%
- Air: 0 - 100%
- Interaction zone: 0.5 - 5.0 mm from handpiece tip to target

OPTICAL

- Laser classification: 4
- Medium: Er, Cr:YSGG
  Erbium, Chromium, Yttrium, Scandium, Gallium Garnet
- Wavelength: 2.78 µm (2780nm)
- Frequency: 5 – 100 Hz
- Average power: 0.1 – 10.0 W
- Power accuracy: ± 20%
- Pulse energy: 0 – 600 mJ
- Pulse duration for "H" mode: 60 µs
- Pulse duration "S" mode: 700 µs
- Handpiece head angles: 70° contra-angle
- Gold HP tip diameter range: 200 – 1200 µm
- Turbo tip focal diameter range: 500-1100 µm
- Output divergence: ≥ 8° per side
- Mode: Multimode
- Aiming Beam: 635nm (red) laser, 1mW max (safety classification 1)*
- Water Level Sensor Beam: 635nm laser, 1mW max (safety classification 1)
- Nominal Ocular Hazard
  Distance (NOHD): 5cm

See separate specifications for iLase Diode Laser Handpiece in the iLase User Manual - Biolase P/N 5400230
*Some Waterlase iPlus units assembled prior to March 2012 might contain a 530nm (green) aiming beam laser.

7 *Indications For Use*

IMPORTANT: Review all Contraindications, Warnings and Precautions presented in Section 7 before proceeding with using this device on patients.

USE OF WATERLASE IPLUS MAY BE INDICATED FOR:

HARD TISSUE

*GENERAL INDICATIONS**

- Class I, II, III, IV and V cavity preparation
- Caries removal
- Hard tissue surface roughening or etching
- Enameloplasty, excavation of pits and fissures for placement of sealants

* For use on adult and pediatric patients

ROOT CANAL HARD TISSUE INDICATIONS

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning.

ENDODONTIC SURGERY (ROOT AMPUTATION) INDICATIONS

- Flap preparation – incision of soft tissue to prepare a flap and expose the bone.
- Cutting bone to prepare a window access to the apex (apices) of the root(s).
- Apicoectomy – amputation of the root end.
- Root end preparation for retrofill amalgam or composite.
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex.

NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.

BONE SURGICAL INDICATIONS

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)➲
- Osteotomy

LASER PERIODONTAL PROCEDURES

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.
- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve

clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

- Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)
- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)
- Osseous crown lengthening
- Waterlase Er,Cr:YSGG assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).
- Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.

*SOFT TISSUE INDICATIONS INCLUDING PULPAL TISSUES**

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Flap preparation – incision of soft tissue to prepare a flap and expose the bone.
- Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions).
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscesses
- Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Root canal debridement and cleaning
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

* For use on adult and pediatric patients

ROOT CANAL DISINFECTION

- Laser root canal disinfection after endodontic instrumentation.

8 Contraindications, Warnings, and Precautions

CONTRAINDICATIONS

All clinical procedures performed with the Waterlase iPlus must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions, which might contraindicate a local procedure. Such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

WARNINGS AND PRECAUTIONS

Federal law restricts this device to sale by or on the order of a licensed medical or dental practitioner.

EYEWEAR

Doctor, patient, assistant, and all others inside the operatory must wear appropriate laser protection eyewear for the 2.78 µm, 940nm wavelengths (OD 4 or greater).

ANESTHESIA

Although in most cases anesthesia may not be required, patients should be closely monitored for signs of pain or discomfort. If such signs are present, adjust settings, apply anesthesia or cease treatment if required.

TREATMENT, TECHNIQUE AND SETTINGS

Only licensed professionals who have reviewed and understood this user manual should use this device. Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, pulse mode, air and water settings, tip type and duration of operation) and make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

HARD TISSUE PROCEDURES

All hard tissue (i.e. enamel, dentin, cementum and bone) procedures must be performed using air and water spray at appropriate settings. Failure to use the spray will result in tissue thermal damage.
The long pulse settings (700 µs) are indicated only for soft tissue applications. Do not use long pulse settings to perform hard tissue procedures.

SOFT TISSUE PROCEDURES

Soft tissue procedures can be performed using two pulse duration settings: (H) short pulse (60 µs) and (S) long pulse (700 µs). The long pulse range is indicated ONLY for soft tissue applications.

CURETTAGE PROCEDURES

Exercise extreme caution when using this device in areas where critical structures (i.e. nerves and vessels) could be damaged, such as in the apical third of the 3rd molar socket. Do not proceed with using the laser if visibility is limited in these areas.

FLUID ENTRAPMENT AND AIR EMBOLISM

Do not direct air or spray toward tissues that may trap air or water. For example, when performing surgical procedures, the clinician should be aware of adjacent soft tissue pockets, cavities, or channels that may collect or entrap air. Always use high-speed suction to remove any excess fluid and avoid directing the spray into deep pockets, cavities or channels such as the crevice resulting from the extraction of a molar. Also, for example, avoid working through soft tissues adjacent to the roots of molars, especially the third inferior molars, which communicate directly with the sublingual and submandibular spaces. Do not use the Waterlase iPlus if it is not possible to access the treatment site without directing air into an area that may collect or entrap air. In general, the same care and precautions should be taken when using the Waterlase iPlus as are taken when using any air and water emitting cutting device, including the high speed drill.

ROOT CANAL PROCEDURES

Instructions andlabeling for root canal therapy procedures are provided with the EndoLase™ RFT Root Canal Therapy Kit.

The Waterlase IPlus is better suited for straight and slightly curved canals. Great care should be taken during instrumentation of curved canals as the endodontic fiber tip may break or perforate through the wall of the curved canal. If during insertion the fiber tip does not advance easily into the canal, do not force the tip inside. A possibility is to pull the fiber out and use an endodontic hand file or a broach to open the path. Do not force the tip and/or activate the laser while moving the tip inside a narrow or curved canal, or through the apex. Place the end of the tip ~2mm from the apex or away from being in contact with the wall of a curved canal. Activate the laser and spray only during the outward stroke when the fiber tip is pulled towards the coronal portion of the canal. For additional information on laser root canal enlargement, review the recommended clinical procedure presented in Appendix C, or the instructions provided with the EndoLase™ RFT Root Canal Therapy Kit.

ROOT CANAL DISINFECTION PROCEDURES

The same precautions and warnings stated above are applicable to root canal disinfection procedures. The fiber tips designed for this indication are the radial emitting RFT2 and RFT3, which have a 200µm and a 300µm diameter, respectively, and come in various lengths to accommodate different canal length sizes. Effective laser root canal disinfection is performed with air and no water spray. Do not exceed the maximum air setting for this procedure, with is 10%.

ADJACENT STRUCTURES

Waterlase iPlus can remove both hard and soft tissues. Therefore, always be aware of adjacent structures and substructures during treatments. Be extremely careful not to inadvertently penetrate or ablate through the apex, the root canal wall or underlying/adjacent tissues. Also, be aware and use extreme caution working on tissue (i.e., bone, root apex, etc.) adjacent to the following structures: maxillary sinus, mental foramen and mandibular canal or any other major anatomical structures (i.e., nerves). Exercise extreme caution when using this device in areas such as pockets, cavities or channels, where critical structures (i.e. nerves, vessels) could be damaged. Do not proceed with using the laser if visibility is limited in these areas.

CLINICAL CONDITIONS

Use a sterile field and aseptic technique with all procedures, especially for surgical interventions.

TISSUE EVALUATION

Any tissue growth (i.e. cyst, neoplasm and other lesions) removed with Waterlase IPlus or conventionally must be submitted to a qualified laboratory for histopathology assessment.

TISSUE CONTACT AND TIP BREAKAGE

Do not contact hard tissues with fiber tip. Hard tissue cutting occurs in non-contact mode with the tip ~0.5 to 3 mm off the surface (3 to 5 mm for Turbo handpiece). The tip is very brittle and fragile, and could break if pressed against tooth or bone tissues or if forced through a narrow or curved path or root canal. Use a bite block to prevent breakage of the tip from swallowing or biting. High speed suction is required to remove any excess fluid and materials resulting from accidental tip breakage.

TIP CHANGING

Failure to correctly replace the tip could result in damage to the fiber tip, handpiece, or affect the emission of laser energy around the tip. A careful review of the instructions on how to replace the tip is recommended.

WATER SPLASHING

Water from spray may splash during treatment. Use protective eyewear and/or a face shield to protect from splashing. Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use the Waterlase iPlus if you cannot clearly see the treatment site.

PLUME REMOVAL

CAUTION: Laser plume may contain viable tissue particulates

Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue during procedures done with laser and minimal or no water spray. Ensure that all appropriate protective equipment (including high-speed suction to remove the plume, appropriate masks, and other protective equipment) is used at all times during procedures with this laser device.

DENTAL MATERIALS

Do not direct energy towards amalgam, gold or other metallic surfaces. Do not direct energy towards dental cements or other similar filling materials. Doing so may damage the Waterlase iPlus tip and delivery system.

TRAINING

Only licensed professionals who have reviewed and understood this User Manual, and know how to correctly operate the system should use this device. Surgical procedures related to soft tissue, osseous, endodontic, or periodontic surgery should only be performed by clincians who have training and experience in Oral, Maxillofacial, Periodontal, or Endodontic Surgery.

9 Clinical Applications

INTRODUCTION

The Waterlase iPlus device is designed to cut and remove hard and soft tissues within the oral cavity. For hard tissue applications, the Waterlase iPlus achieves its uniquely diverse capabilities through the process of light absorption by water. The proprietary flexible fiber optic system and handpiece delivers both optical energy and atomized water to the treatment site for precise hard tissue removal.

To efficiently remove hard and soft tissues it helps to understand the unique nature of the Waterlase iPlus device. Waterlase iPlus operates unlike traditional dental instruments or devices and technique must be practiced and perfected to ensure efficient operation.

Please be aware that the Waterlase iPlus system removes hard tissues through a hydrophotonic process with the fiber tip applied in a non-contact mode. The fiber tip has to be positioned at approximately 0.5 to 3 mm from the surface (3 to 5 mm for Turbo handpiece) and great care must be taken not to brush or push the tip into tissue during treatments. The tip is fragile and may break if knocked or pressed into the tooth or other instruments.

For soft tissue applications, cutting is achieved in a contact or non-contact mode by application of direct laser energy either with or without water cooling and hydration spray. A detailed description of the techniques for cutting hard and soft tissues with Waterlase iPlus is presented in the following subsections.

Please study this Section carefully, practice on tissue models and attend a Waterlase iPlus training seminar before using this device in a clinical situation.

HARD TISSUE CUTTING

Hard tissue cutting is achieved through a unique process described as hydrophotonic cutting. This process refers to the removal of tissue with laser energized water and results in quick and clean hard tissue removal.

Once settings have been selected for enamel, dentin or cementum cutting, carefully position the fiberoptic tip approximately 5 mm away from the targeted tissue site to test the laser system. Step on the footswitch, and water spray and power will be immediately delivered to the tissue site. You will notice a distinct, gentle “popping” noise as water expand from laser energy absorption. At this position (5 mm away from targeted tissue , or slightly more for Turbo handpiece), there will be minimal to no cutting effect. If the water spray is not flowing or no distinct popping noise is present, stop the system immediately. Refer to the troubleshooting section of this Manual for instructions or call your local representative for assistance.

NOTE: Always remember that laser power and, therefore, hydrophotonic energy are delivered from the very end of the tip. Tissue cutting technique can be characterized as "end cutting," whereas the mechanical drill is known as a "side cutting" instrument.

If the water flow and "popping" noise are OK, gently and slowly move the handpiece tip closer to the targeted tissue site. As you approach the treatment area you may notice a large accumulation of water. Use high speed suction as necessary to keep the field clear. Because of the great differences between traditional dental drill and Waterlase iPlus cutting techniques, it is very important to have the exact treatment location visually identified before and during treatment.

Maintain a distance of 0.5 to 3 mm between the fiber tip and the treatment tissue (3 to 5 mm for Turbo handpiece) while moving the handpiece over the tissue surface as required. Keep in mind that cutting speed is determined primarily by parameter settings and distance from tissue, not by rapid hand movement as with the high-speed drill. Gently and slowly move the handpiece in a circular, brushing or in-and-out motion as required to remove desired tissues or materials. Unlike traditional dental instruments, with the Waterlase iPlus, the slower you move the handpiece tip the quicker you will remove tissue.

Cutting efficiency will vary depending upon the power setting, tip diameter, and spray configuration. If you feel that the system is working slowly at the selected power setting, you can adjust the air and water spray settings. You will notice that clinical efficiency depends upon power as well as spray. As you gain experience with the Waterlase iPlus you will be able to determine spray and power efficiency from the sound of the popping water droplets. A sharper, more distinct popping sound represents a higher cutting rate.

After you have completed treatment, release the footswitch and carefully remove the handpiece from the patient's mouth. Do not hit the handpiece tip into teeth or other instruments while removing the handpiece or the tip may break. To remove the tip use the tip remover tool. Place a new tip on the tip plug to avoid contamination and damage to the handpiece. At the end of the treatment the handpiece and tip must be autoclaved (see Handpiece and Tip Cleaning and Sterilization later in this section) , except for single-use tips (such as ZipTips, RFPT, RFT, and some others) which should be disposed of in a biohazard medical waste sharps container. Single-use tips should not be reused.

SOFT TISSUE INCISION, EXCISION AND ABLATION

Soft tissue procedures are performed with direct laser energy, either with or without the water spray. The water spray settings are generally lower for soft tissue than for hard tissue. During soft tissue cutting, the air and water spray hydrates and cools the target. There are two pulse settings for soft tissue applications: (1) a short pulse setting of 60 µs, and (2) a long pulse setting range of 700 µs. The second range of pulses is indicated only for soft tissue applications.

For these procedures, select appropriate settings or presets as described in the GUI instructions, Section 5. Once settings or presets have been selected, carefully place the tip in contact with the tissue to be incised. Step on the footswitch and start moving the tip along the tissue surface by applying light pressure. The incision will be noticed immediately after laser activation. Bleeding is controlled through reduction of the water setting. For superficial lesions or hemostasis, the tip must be placed out of contact at approximately 1-3 mm off the surface. Effective hemostasis is achieved when the water spray is turned off.

PROCEDURE GUIDELINES

For guidelines on specific dental and surgical procedures with the Waterlase iPlus, please refer to Appendix C.

PRESETS FOR SOFT AND HARD TISSUE PROCEDURES

As described before, Waterlase iPlus has the option of nine user programmable presets stored in the system memory. There are about 50 pre-set settings to select from or adjust to appropriate values for the procedure. Always start treatment at the lowest recommended power setting, and increase as required using clinical judgment. The values pre-programmed with the system are suggested values only. Use your clinical judgment to adjust the individual values for Power, Water, Air, pulse repetition rate and mode S/H in order to compensate for variations in tissue composition, density and, or thickness. When a particular combination of customized values is especially effective and useful, you have the option to then store the values in the system as a new Preset. Instructions for storing a new group of preset settings are provided in Section 5: Settings/Memory Menu.

The Waterlase iPlus may be used for the applications listed in Section 7: Waterlase iPlus Indications for Use, Table of Indications for Use. If you are not sure which preset or settings to use, please refer to the suggested settings on the device or use your clinical experience to make appropriate adjustments. Attend training courses and experiment on model tissues before using the Waterlase iPlus on patients.

FIBER TIP CALIBRATION CHART

Refer to Appendix D Tips: Suggested Clinical Specifications to review the different characteristics and calibration factors for the Waterlase iPlus tips. To calculate the expected power output from different families of tips, follow the instructions below.

- Select the tip for the procedure.
- Review Appendix D Tips: Suggested Clinical Specifications to select appropriate calibration factors for the selected tip.
- Use Calibration Menu to read the actual power coming out of the tip or calculate the power emitted at the tip by multiplying the display power by the calibration factor of the tip type. Remember that for a calibration factor of 1, the emitted power is the same as the display. Also, actual emitted power could vary as much as ±20%.

CALCULATING EMITTED POWER WITH TIP ATTACHMENT:

Example 1:	Example 2:
Tip Type: MZ4	Tip Type: RFT2
Calibration Factor: 0.90	Calibration Factor: 0.55
Display Power: 2W	Display Power: 1W
Then the Power Emitted is:	Then the Power Emitted is:
2W x 0.90 = 1.80 W	1W x 0.55 = 0.55 W

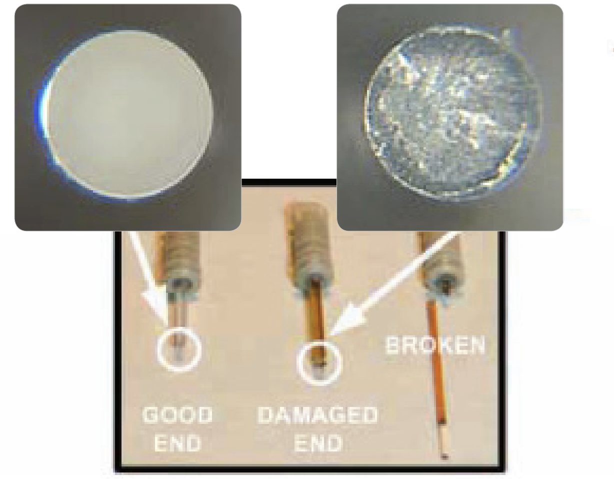

BROKEN
GOOD END
DAMAGED END

FIG 9.1

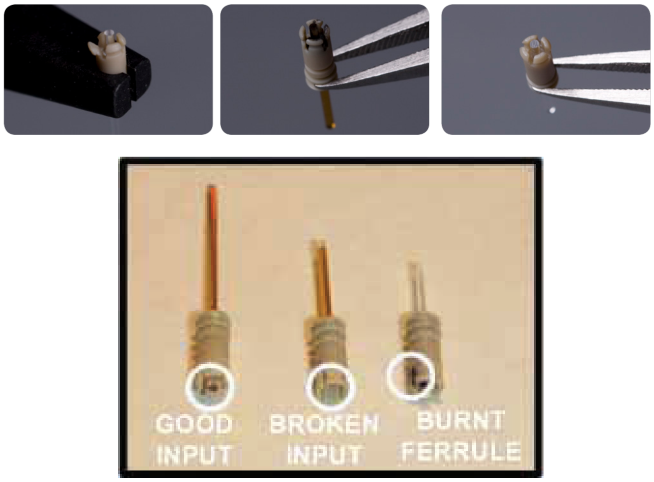

GOOD INPUT
BROKEN INPUT
BURNT FERRULE

FIG 9.2

USE OF THE AIMING BEAM.

1. Set system to “Ready” mode and point handpiece towards a white surface. The visible spot from the aiming beam should be well confined or have several concentric circles;

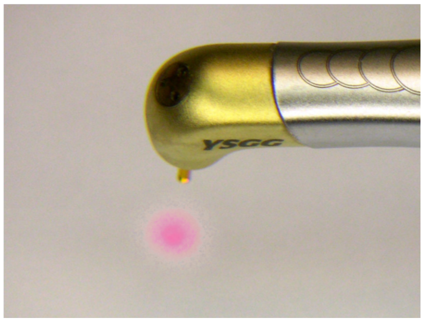


FIG 9.3

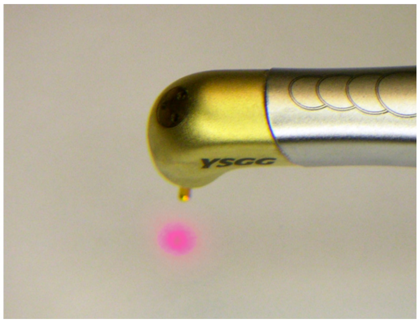


FIG 9.4

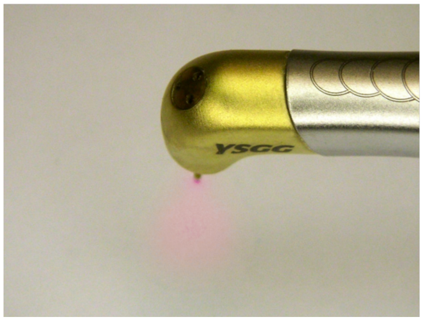


FIG 9.5

2. While still in the “Ready” mode, check that the end of the tip does not “glow.” The visible beam should not be visible when observed from the side (end of the tip must be dry);

PRESETS TABLE

Restorative *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Class I	ComfortPrep	Gold	MZ10	9.00	15	H		70	90
			MZ8*	6.00	15	H		50	80
			MZ6	3.75	15	H		30	60
			MZ5	3.00	15	H		30	60
			MZ4	2.00	15	H		30	60
			MT4	2.00	15	H		30	60
			MGG6	3.75	15	H		30	60
			MC6	3.75	15	H		30	60
			MS75	5.50	15	H		50	80
		Turbo	MX11	9.00	15	H		70	90
			MX9*	6.00	15	H		50	80
			MX7	3.75	15	H		30	60
			MX5	2.00	15	H		30	60
	RapidPrep	Gold	MZ10	10.00	20	H		70	90
			MZ8*	8.00	20	H		70	90
			MZ6	5.00	20	H		50	80
			MZ5	4.00	20	H		30	60
			MZ4	2.75	20	H		30	60
			MT4	2.50	20	H		30	60
			MGG6	5.00	20	H		50	80
			MC6	5.00	20	H		50	80
			MS75	7.25	20	H		50	80
		Turbo	MX11	10.00	20	H		70	90
			MX9*	8.00	20	H		70	90
			MX7	5.00	20	H		50	80
			MX5	2.50	20	H		30	60
	BondPrep	Gold	MZ10	7.00	50	H		50	80
			MZ8*	4.50	50	H		30	60
			MZ6	2.50	50	H		30	60
			MZ5	2.00	50	H		30	60
			MZ4	1.50	50	H		30	60
			MT4	1.25	50	H		30	60
			MGG6	2.25	50	H		30	60
			MC6	2.50	50	H		30	60
			MS75	3.75	50	H		30	60
		Turbo	MX11	6.25	50	H		50	80
			MX9*	4.50	50	H		30	60
			MX7	2.50	50	H		30	60
			MX5	1.25	50	H		30	60

Restorative **(continued)** *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Class II	ComfortPrep	Gold	MZ10	9.00	15	H		70	90
			MZ8*	6.00	15	H		50	80
			MZ6	3.75	15	H		30	60
			MZ5	3.00	15	H		30	60
			MZ4	2.00	15	H		30	60
			MT4	2.00	15	H		30	60
			MGG6	3.75	15	H		30	60
			MC6	3.75	15	H		30	60
			MS75	5.50	15	H		50	80
		Turbo	MX11	9.00	15	H		70	90
			MX9*	6.00	15	H		50	80
			MX7	3.75	15	H		30	60
			MX5	2.00	15	H		30	60
	RapidPrep	Gold	MZ10	10.00	20	H		70	90
			MZ8*	8.00	20	H		70	90
			MZ6	5.00	20	H		50	80
			MZ5	4.00	20	H		30	60
			MZ4	2.75	20	H		30	60
			MT4	2.50	20	H		30	60
			MGG6	5.00	20	H		50	80
			MC6	5.00	20	H		50	80
			MS75	7.25	20	H		50	80
		Turbo	MX11	10.00	20	H		70	90
			MX9*	8.00	20	H		70	90
			MX7	5.00	20	H		50	80
			MX5	2.50	20	H		30	60
	BondPrep	Gold	MZ10	7.00	50	H		50	80
			MZ8*	4.50	50	H		30	60
			MZ6	2.50	50	H		30	60
			MZ5	2.00	50	H		30	60
			MZ4	1.50	50	H		30	60
			MT4	1.25	50	H		30	60
			MGG6	2.25	50	H		30	60
			MC6	2.50	50	H		30	60
			MS75	3.75	50	H		30	60
		Turbo	MX11	6.25	50	H		50	80
			MX9*	4.50	50	H		30	60
			MX7	2.50	50	H		30	60
			MX5	1.25	50	H		30	60

Restorative **(continued)** *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Class III, IV, V	ComfortPrep	Gold	MZ10	6.00	15	H		50	80
			MZ8*	4.00	15	H		30	60
			MZ6	2.50	15	H		30	60
			MZ5	2.00	15	H		30	60
			MZ4	1.50	15	H		30	60
			MT4	1.25	15	H		30	60
			MGG6	2.50	15	H		30	60
			MC6	2.50	15	H		30	60
			MS75	3.50	15	H		30	60
		Turbo	MX11	6.00	15	H		50	80
			MX9*	4.00	15	H		30	60
			MX7	2.50	15	H		30	60
			MX5	1.25	15	H		30	60
	RapidPrep	Gold	MZ10	8.00	20	H		70	90
			MZ8*	5.25	20	H		50	80
			MZ6	3.25	20	H		30	60
			MZ5	2.50	20	H		30	60
			MZ4	2.00	20	H		30	60
			MT4	1.75	20	H		30	60
			MGG6	3.25	20	H		30	60
			MC6	3.25	20	H		30	60
			MS75	4.75	20	H		30	60
		Turbo	MX11	8.00	20	H		70	90
			MX9*	5.25	20	H		50	80
			MX7	3.25	20	H		30	60
			MX5	1.75	20	H		30	60
	BondPrep	Gold	MZ10	7.00	50	H		50	80
			MZ8*	4.50	50	H		30	60
			MZ6	2.50	50	H		30	60
			MZ5	2.00	50	H		30	60
			MZ4	1.50	50	H		30	60
			MT4	1.25	50	H		30	60
			MGG6	2.25	50	H		30	60
			MC6	2.50	50	H		30	60
			MS75	3.75	50	H		30	60
		Turbo	MX11	6.25	50	H		50	80
			MX9*	4.50	50	H		30	60
			MX7	2.50	50	H		30	60
			MX5	1.25	50	H		30	60

Soft Tissue *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Gingival Recontour	Rapid Cut	Gold	MT4*	2.50	75	H		40	20
			MZ6	3.25	75	H		40	20
			MGG6	3.25	75	H		40	20
			MZ5	2.75	75	H		40	20
	Smooth Cut	Gold	MT4*	2.50	50		S	20	20
			MZ6	4.00	50		S	20	20
			MGG6	4.00	50		S	20	20
			MZ5	3.50	50		S	20	20
	Tissue Plasty	Gold	MZ6*	2.25	50		S	10	10
			MZ5	2.00	50		S	10	10
			MGG6	2.25	50		S	10	10
			MC3	2.00	50		S	10	10
Frenectomy	Rapid Cut	Gold	MZ5*	2.75	50	H		40	20
			MT4	2.50	50	H		40	20
			MC3	2.75	50	H		40	20
	Smooth Cut	Gold	MZ5*	3.50	50		S	20	20
			MT4	2.50	50		S	20	20
			MC3	3.50	50		S	20	20
	Tissue Plasty	Gold	MZ5*	2.00	50		S	10	10
	Laser Bandage Dry	Gold	MZ5*	0.50	30	H		OFF	20
Biopsy	Rapid Cut	Gold	MZ5*	2.75	50	H		40	20
			MT4	2.50	50	H		40	20
			MC3	2.75	50	H		40	20
	Smooth Cut	Gold	MZ5*	3.50	50		S	20	20
			MT4	2.50	50		S	20	20
			MC3	3.50	50		S	20	20
	Tissue Plasty	Gold	MZ5*	2.00	50		S	10	10
			MC3	2.00	50		S	10	10
	Laser Bandage Dry	Gold	MZ5*	0.50	30	H		OFF	20

Endo *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Root Canal Therapy	Access	Gold	MZ10	10.00	20	H		70	90
			MZ8*	8.00	20	H		70	90
			MZ6	5.00	20	H		50	80
			MZ5	4.00	20	H		30	60
			MZ4	2.75	20	H		30	60
			MT4	2.50	20	H		30	60
			MGG6	5.00	20	H		50	80
			MC6	5.00	20	H		50	80
			MS75	7.25	20	H		50	80
		Turbo	MX11	10.00	20	H		70	90
			MX9*	8.00	20	H		70	90
			MX7	5.00	20	H		50	80
			MX5	2.50	20	H		30	60
	Conventional Filing								
	Clean & Shape	Gold	RFT2*	1.25	50	H		24	34
			RFT3	2.25	50	H		24	34
	Disinfection	Gold	RFT2*	0.75	20	H		OFF	10
			RFT3	1.50	20	H		OFF	10
Pulpotomy	Access	Gold	MZ10	10.00	20	H		70	90
			MZ8*	8.00	20	H		70	90
			MZ6	5.00	20	H		50	80
			MZ5	4.00	20	H		30	60
			MZ4	2.75	20	H		30	60
			MT4	2.50	20	H		30	60
			MGG6	5.00	20	H		50	80
			MC6	5.00	20	H		50	80
			MS75	7.25	20	H		50	80
		Turbo	MX11	10.00	20	H		70	90
			MX9*	8.00	20	H		70	90
			MX7	5.00	20	H		50	80
			MX5	2.50	20	H		30	60
	Coagulation	Gold	MZ8*	2.00	50		S	OFF	20
			MZ5	1.00	50		S	OFF	20
			MS75	1.75	50		S	OFF	20
			MGG6	1.50	50		S	OFF	20
			MZ6	1.50	50		S	OFF	20

Endo **(continued)** *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Apicoectomy	Flap	Gold	MT4*	2.50	20	H		20	40
			MZ5	3.00	20	H		20	40
	Osseous Access	Gold	MZ8*	4.50	25	H		20	40
			MZ5	3.00	25	H		20	40
			MGG6	2.50	25	H		20	40
			MZ6	2.50	25	H		20	40
	Root Amputation	Gold	MZ8*	8.50	25	H		70	90
			MZ5	6.00	25	H		50	80
			MGG6	5.00	25	H		50	80
			MZ6	5.00	25	H		50	80
		Turbo	MX7	7.00	25	H		70	90
	Bone Debride	Gold	MZ8*	3.75	100	H		OFF	10
			MZ5	2.00	100	H		OFF	10
			MGG6	2.00	100	H		OFF	10
			MZ6	2.00	100	H		OFF	10

Perio *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Pocket Therapy Closed	Inner Epi Removal	Gold	RFPT5*	1.5	30	H		15	15
	Calculus Removal	Gold	RFPT5*	3.5	75	H		40	20
	Outer Epi Removal	Gold	RFPT5*	1.5	30	H		20	11
			MZ6	1.5	30	H		20	11
			MC3	1.5	30	H		20	11
			MGG6	1.5	30	H		20	11
			MS75	2.25	30	H		20	11
			MZ8	2.5	30	H		20	11
Pocket Therapy Open	Flap	Gold	MT4*	2	50	H		40	20
			MZ5	2.5	50	H		40	20
	Calculus Removal	Gold	MC3*	3.5	75	H		40	20
	Osseous Recontour	Gold	MC3*	2.5	30	H		55	30
			MZ6	2.5	30	H		55	30
			MGG6	2.5	30	H		55	30
			MS75	3.5	30	H		65	40
			MZ8	4	30	H		65	40
	Outer Epi Removal	Gold	MC3*	1.5	30	H		20	11
			MZ6	1.5	30	H		20	11
			MGG6	1.5	30	H		20	11
			MS75	2.25	30	H		20	11
			MZ8	2.5	30	H		20	11

Perio (continued) *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Osseous CL Closed	Gingival Recontour	Gold	MT4*	2.5	75	H		40	20
			MZ5	2.75	75	H		40	20
	Osseous Recontour	Gold	MC3*	2.5	30	H		55	30
			MZ6	2.5	30	H		55	30
			MGG6	2.5	30	H		55	30
			MS75	3.5	30	H		65	40
			MZ8	4	30	H		65	40
	Bone Plasty	Gold	MZ6*	2.5	50	H		40	20
			MGG6	2.5	50	H		40	20
			MC3	2.5	50	H		40	20
			MZ8	4	50	H		40	20
	Tissue Plasty	Gold	MZ6*	2.25	50		S	10	10
			MGG6	2.25	50		S	10	10
			MZ8	3.5	50		S	20	20
			MC3	2.25	50		S	10	10
Osseous CL Open	Gingival Recontour	Gold	MT4*	2.5	75	H		40	20
			MZ5	2.75	75	H		40	20
	Flap	Gold	MT4*	2	50	H		40	20
			MZ5	2.5	50	H		40	20
	Osseous Recontour	Gold	MC3*	2.5	30	H		55	30
			MZ6	2.5	30	H		55	30
			MGG6	2.5	30	H		55	30
			MS75	3.5	30	H		65	40
			MZ8	4	30	H		65	40
	Tissue Plasty	Gold	MZ6*	2.25	50		S	10	10
			MGG6	2.25	50		S	10	10
			MZ8	3.5	50		S	20	20
			MC3	2.25	50		S	10	10

Implants *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Implant Recovery	Rapid Cut	Gold	MZ5*	2.75	75	H		40	20
			MT4	2.50	75	H		40	20
	Osseous Access	Gold	MZ6*	6.00	25	H		50	80
			MZ8	8.50	25	H		70	90
			MGG6	6.00	25	H		50	80
	Emergence Profile	Gold	MZ5*	2.00	100	H		10	10
			MC3	2.00	100	H		10	10
Peri-implantitis	[redacted]								

Expanded *indicates the factory-programmed tip selection

Procedure	Procedure Step	Handpiece	Tip Types	Power	Hz	Mode		Spray, %	
		PREF	PREF	NOM	NOM	H	S	Water	Air
Troughing	Rapid Cut	Gold	MZ6*	2.75	75	H		40	20
			MGG6	2.75	75	H		40	20
	Hemostasis	Gold	MZ6*	0.50	30		S	OFF	20
			MGG6	0.50	30		S	OFF	20
Laser Bandage	Wet	Gold	MZ6*	0.50	30	H		5	20
			MGG6	0.50	30	H		5	20
			MZ5	0.50	30	H		5	20
	Dry	Gold	MZ6*	0.50	30	H		OFF	20
			MGG6	0.50	30	H		OFF	20
			MZ5	0.50	30	H		OFF	20

10 Cleaning and Sterilization

CAUTION: Handpieces and laser tips must be sterilized prior to initial use and cleaned and sterilized between patients. Disposable single use tips, i.e. quarts (glass) must be disposed of in a biohazard medical waste Sharps container.

CAUTION: Cleaning must be performed within a maximum of 1 hour after the procedure prior to sterilization.

CAUTION: Use only MANUAL CLEANING described below. Other cleaning methods should be avoided since water entering the portals of the exhaust ring may damage the fiber optics inside the handpiece.

STEP 1—CLEANING PROCESS

The cleaning process is intended to remove blood, protein and other potential contaminants and to reduce the quantity of particles, microorganisms and pathogens present from the handpieces, laser tip surfaces and crevices. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the laser handpiece and tips while wearing goggles, masks, gloves and shields.

1. Upon completion of the procedure, ensure that laser tips remains installed in the handpiece. Do not remove the tip.

2. Install the Rear Plug in the handpiece. During the cleaning procedure care must be taken to prevent the cleaning solution and rinse water from entering the portals of the exhaust ring.

3. Rinse the handpiece with the tip under lukewarm water (22 – 43°C) for 10 seconds to remove gross soil.

4. Prepare a cleaning solution per the manufacturer’s instructions. Use a commercially-available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol® or similar enzymatic presoak and cleaner. Follow instructions for disposal of used solution.

5. Soak a piece of gauze sufficient to wrap the handpiece in the cleaning solution. Squeeze out the excess liquid and wrap the handpiece with the installed tip. Leave it wrapped for a minimum of 10 minutes.

6. Unwrap the handpice and the tip. Using a soft-bristled brush dipped in the cleaning solution, gently brush around the tip ferrule, crevices and other hard-to-clean areas for 15 seconds. The brush should be wet but not dripping. Avoid contact with the exhaust ring and portals.

7. Rinse the handpiece under lukewarm running, tap water (22-43°C) for 10 seconds.

8. Dry the handpiece with a lint-free cloth.

9. Visually inspect the handpiece for any residual soil. If present, repeat steps 5 through 8, until any residual soil is removed.

10. Using the Tip Remover or Revolving Tip Holder, remove the tip from the handpiece per steps described below.

11. Gently wipe the orifice of the handpiece head with a dry lint-free cloth making sure to remove any soil/debris that may have accumulated in the crevice between the laser tip and the handpiece.

Tip removal using the Tip Remover or Revolving Tip Holder

- Slide the handpiece laterally toward the Tip Remover or Revolving Tip Holder [Fig. 10.1]
- Place your thumb against the selected tip slot to prevent laser tip from falling out of the Tip Holder when disconnecting from the handpiece

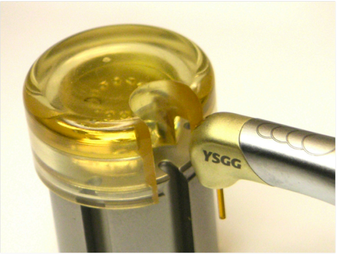


FIG 10.1

- Carefully lift the handpiece to disengage the tip ferrule from the handpiece head
- Use tweezers to slide the tip out from the Tip Holder or Tip Remover [Fig. 10.2]

12. If the tip is a single use accessory, dispose of in a biohazard medical waste Sharps container. If the tip is reusable, rinse it with distilled water for 10 seconds. Dry with lint-free cloth.

13. Visually inspect the tip for any residual soil. If present, repeat step 12, above, until residual soil is removed.

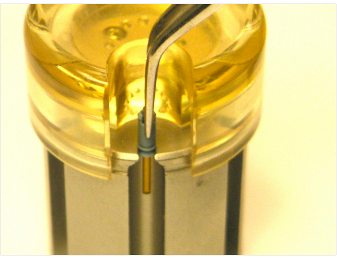


FIG 10.2

STEP 2—HANDPIECE STEAM STERILIZATION

The Steam sterilization process is intended to destroy infectious microorganisms and pathogens.

NOTE: Always perform the procedure immediately after cleaning and prior to use and only use FDA-cleared (USA) or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray.

1. Prior to sterilization, remove the Rear and Tip Plugs, if installed.
2. Place the handpiece inside a single-wrap, self-sealed sterilization pouch.
3. The tips may be sterilized in the Tip Holder. Place the individual tips or the Tip Holder loaded with tips inside a separate single-wrap self-sealed pouch.
4. Place the pouches on an autoclave tray. Take care when handling the handpiece and tips.
5. Do not stack other instruments on top of the pouches.
6. Place the tray into the autoclave chamber and set appropriate cycle as recommended below.

Type of sterilizer	Temperature	Min Time	Drying Time
Gravity Displacement	132°C (270°F)	15 minutes	15 - 30 minutes
Dynamic-Air-Removal (Pre-Vacuum)	132°C (270°F)	4 minutes	20 - 30 minutes
	134°C EU only	4 minutes	20 - 30 minutes

7. Upon completion of the cycle, the handpiece and tips must remain in the sterilization pouches prior to use to ensure sterility.

8. To reassemble the tip, remove the tip from the sterilization pouch with tweezers and insert it into the Tip Remover or Tip Holder (if not in the Tip Holder). Follow the INSTALLING AND CHANGING THE TIP IN THE HANDPIECE procedure detailed in Section 4.

WARNING: Warning: Repeated processing of the handpiece and reusable tips may reduce the useful life of these devices. Check the handpiece for damage or wear prior to each use. The handpiece should be free of nicks, distortion, corrosion or other signals of mechanical degradation. If damage or wear is observed, discard the handpiece.

Use of damaged or worn tips may cause damage to the delivery system and will compromise the clinical performance of the iPlus Laser System. The tips must be inspected prior to each use for damage or wear as described under TIP INSPECTION in Section 9.

11 Maintenance

BASIC MAINTENANCE

MIRROR CHECK AND CLEANING

NOTE: If performance of the delivery system is questioned and the Tip is in good condition, check the Mirror for damage or contamination.

WARNING: Use of contaminated or damaged Mirror will cause damage of the Fiber Delivery System.

Set system in the “Standby” mode, navigate to the illumination screen (Fig 5.10), and remove the Tip;

MIRROR INSPECTION AND CLEANING

1. Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform and well confined. If dark areas and irregularities are present, inspect the mirror; (Applies to both Turbo and Gold handpieces).

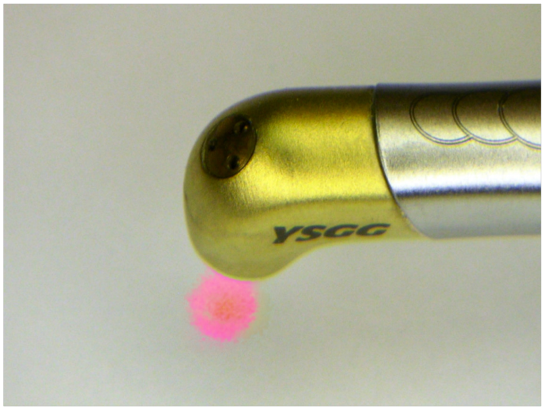


FIG 11.1

NOTE: If the plastic tip ferrule is continuously getting damaged at the input end, mirror should be checked and cleaned. Mirror alignment should be checked.

2. To inspect the mirror, remove it following proper procedure (see: Changing the Waterlase iPlus Handpiece Mirror);

3. Mirror can be contaminated or damaged;

4. Contaminated mirror can be cleaned and with cotton swab, moistened with optical grade acetone or alcohol:

- Place wet swab over the mirror surface and wait for ~5sec for solvent to soften the contaminating material;
- Wipe off the contamination by quick turn and removal of the swab;
- Repeat several times until all contamination is removed.

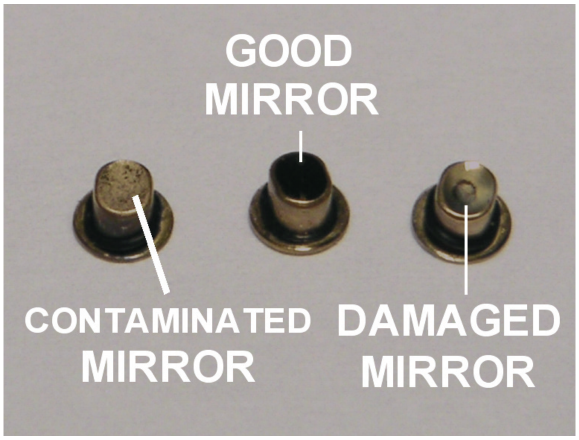


FIG 11.2

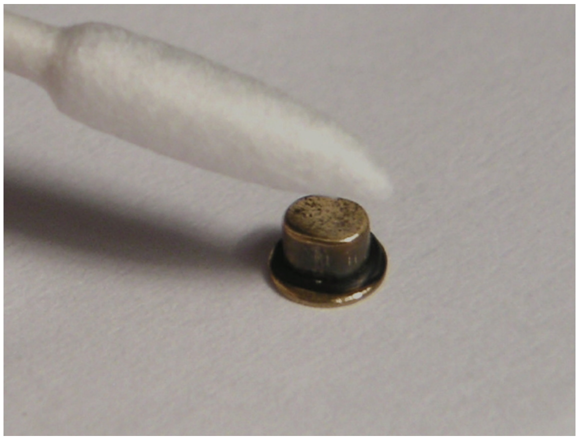


FIG 11.3

5. If mirror has remaining burn marks or scratches, it should be replaced;

6. While mirror is removed and it has contamination or burn marks, clean the internal reflector inside handpiece head with long cotton swab, moistened with acetone or alcohol;

7. Install the new or cleaned mirror and check proper alignment.

MIRROR ALIGNMENT CHECK

1. Point the Handpiece towards a white surface. The visible spot of the aiming beam should be clear, uniform and well confined;

2. If spot is confined on one side and has satellite-type reflection (smile) on the opposite side, mirror alignment is questioned;

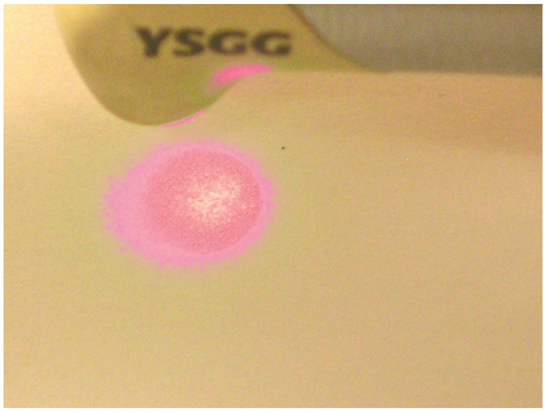


FIG 11.4

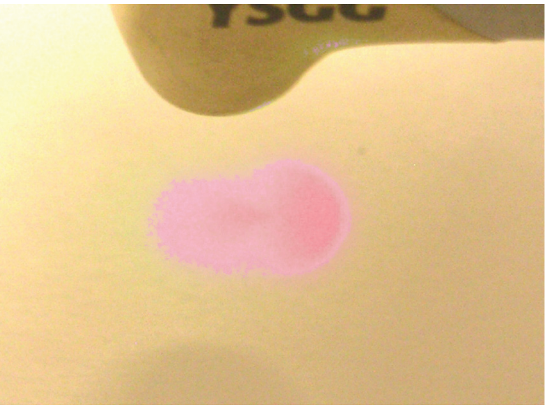


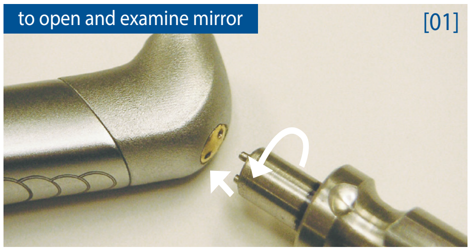
FIG 11.5

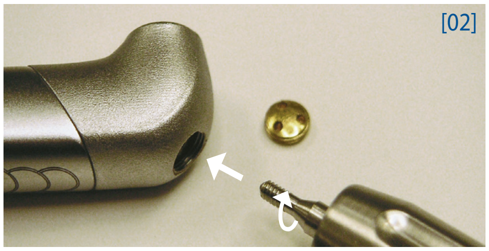
3. To improve alignment, remove the mirror and turn it 180 degrees (see Second. Changing the Waterlase iPlus Handpiece Mirror). If this does not help, replace the handpiece. If that does not help, replace the trunk fiber;

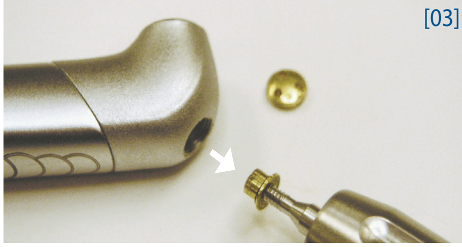
NOTE: If the plastic tip ferrule is continuously getting damaged at the input end, mirror alignment should be questioned.

CHANGING THE HANDPIECE MIRROR

to open and examine mirror


[01]


[02]


[03]

[01] Insert the 3-pin side of the tool onto 3 holes of the cap in a handpiece head. Make sure all pins fit snugly. Turn counterclockwise approximately 3 turns to unscrew the cap. Remove the cap from the tool and place in a safe place.
Do not turn handpiece with the opening down, otherwise the mirror may fall out and be lost.

[02] Insert the other side of the tool perpendicular to the plane of the backside of the mirror inside the opening. Screw the threaded side of the tool into the mirror by turning tool clockwise 2-2.5 full turns. Do not thread all the way into the mirror for easier release of the mirror later.

[03] Pull mirror straight out from the head opening. Grab the mirror with fingers or tweezers and unscrew from the tool (wear gloves or fingertips – do not handle mirror with bare hands). If you touch the mirror surface, gently clean it with alcohol. Thread new mirror onto the mirror replacement tool.

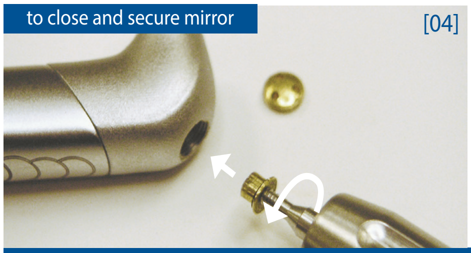
Note If mirror has burn marks, clean the internal surfaces of the handpiece head with a long cotton swab, moistened with alcohol.

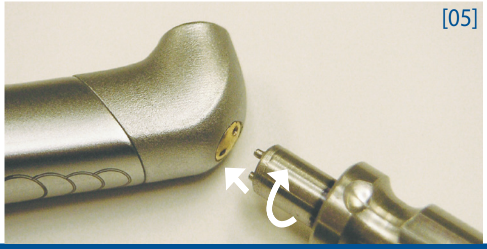
99.9% pure isopropyl alcohol is required for the use of this product. Please order from your authorized distributor (Biolase P/N 3000251).

To insert and secure the NEW mirror into the handpiece, repeat whole procedure in reverse order.

Attention ! Mirror is oval symmetrical, make sure of proper orientation when inserting the mirror into the handpiece head.

to close and secure mirror


[04]


[05]

part no. 5200126 Rev. E

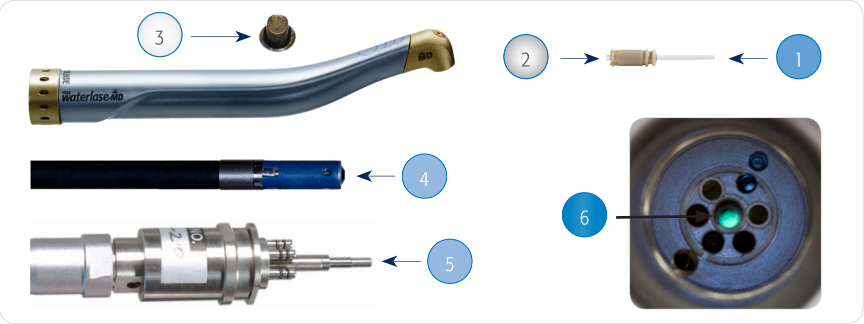
To reorder this kit (part no. 7200105S) or additional mirrors (part no. 6200280S), call BIOLASE Customer Service at 1.888.424.6527

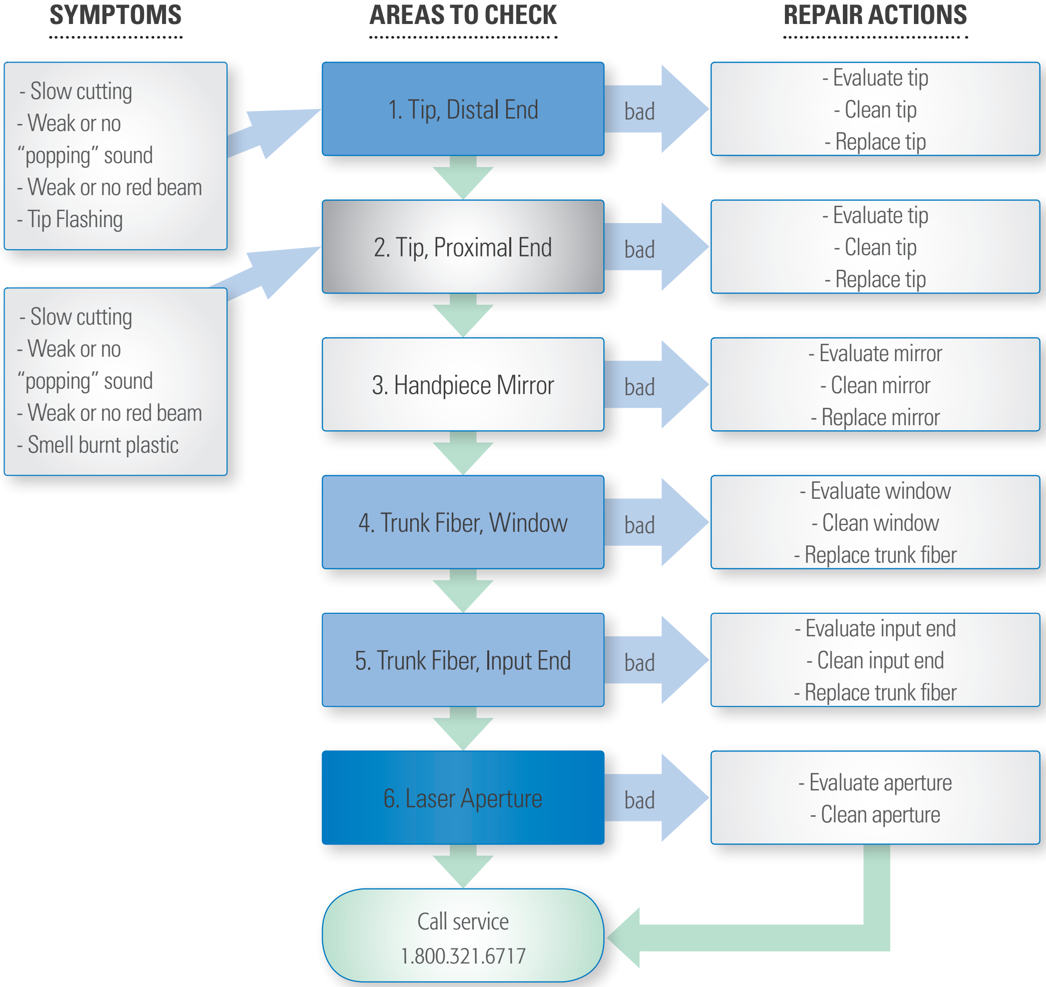
Biolase Technology, Inc. - 4 Cromwell - Irvine, CA 92618 - 949.361.1200 - biolase.com ECREP MT Promedt Consulting GmbH - Altenhofstrasse 80 - D-66386 St.Ingbert/Germany - +496894581020 - www.mt-procons.com

TROUBLESHOOTING THE DELIVERY SYSTEM

Using the Flowchart:
Find the Symptom – on the left.
Inspect the Areas to Check – in the middle.
Perform the recommended Repair Action – to the right.
Use the Repair Actions to direct you to the appropriate corrections in this reference guide.

⚠ Warning: Early discovery and repair of problems will improve the dependability of the laser system and prevent further problems.


3
2
1
Waterlase MD
4
6
5


SYMPTOMS
AREAS TO CHECK
REPAIR ACTIONS
- Slow cutting
- Weak or no "popping" sound
- Weak or no red beam
- Tip Flashing
- Slow cutting
- Weak or no "popping" sound
- Weak or no red beam
- Smell burnt plastic
1. Tip, Distal End
bad
- Evaluate tip
- Clean tip
- Replace tip
2. Tip, Proximal End
bad
- Evaluate tip
- Clean tip
- Replace tip
3. Handpiece Mirror
bad
- Evaluate mirror
- Clean mirror
- Replace mirror
4. Trunk Fiber, Window
bad
- Evaluate window
- Clean window
- Replace trunk fiber
5. Trunk Fiber, Input End
bad
- Evaluate input end
- Clean input end
- Replace trunk fiber
6. Laser Aperture
bad
- Evaluate aperture
- Clean aperture
Call service
1.800.321.6717

FIBER CHECK

NOTE: Regularly inspect the end of the Fiber Shaft. Always inspect and clean the Protective Window at the end of the Fiber Shaft after input end of the Tip or Handpiece mirror were damaged.

WARNING: Use of dirty or contaminated Protective Window will cause damage of the Fiber Delivery System.

1. Disconnect the Handpiece following proper procedure;

2. Verify laser is in the "Standby" mode;

3. Check polished reflective surface of the window in the middle of the Fiber Shaft;

4. Clean with cotton swab and isopropyl alcohol if surface is contaminated;

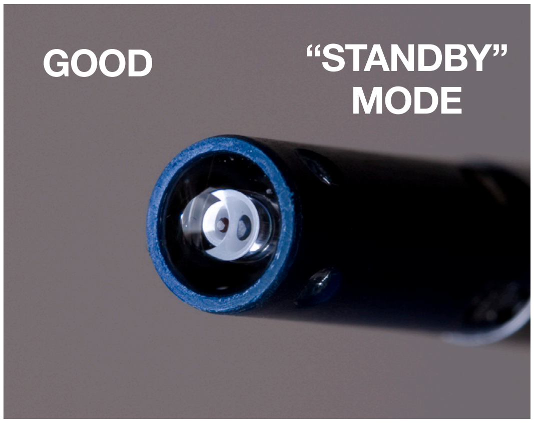


FIG 11.7

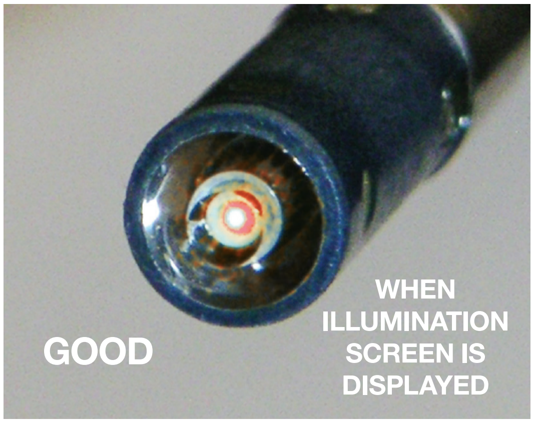


FIG 11.6

➔ If damage found (crater in the middle of the window), replace Fiber Delivery System;

5. Wear protective eyewear. Navigate to the illumination screen (Fig 5.10).

6. Visible aiming beam and illumination fibers should be lit (adjust brightness, if necessary). If aiming beam is not visible, replace Fiber Delivery System.

DANGER: Invisible and/or visible laser radiation – Avoid eye or skin exposure to direct or scattered radiation.

ANNUAL MAINTENANCE

The Waterlase iPlus should be serviced annually by a qualified, trained and certified technician. During the annual visit the system flash lamp will be inspected and the system will be calibrated. The entire laser cavity and optical train will be cleaned. All relevant electronic circuits will be calibrated. Filters and cooling fluid will be changed as well. Please contact your local representative to discuss extended service contracts and annual maintenance options.

DELIVERY SYSTEM

The fiber delivery system and handpiece represent high technology laser transmitting components. Depending on use, and due to the precision involved in the manufacture and alignment of the laser beam and internal optics, the components may need to be periodically replaced to maintain tissue cutting efficiency. Properly following the operating and maintenance instructions of this Manual will increase the delivery system's lifetime.

LASER CONSOLE

The laser console contains electronic and mechanical components that are thoroughly checked when the unit is first shipped, as well as when a trained engineer services the unit. Depending on the use of the unit, some of these components may require periodic servicing and/or replacement between annual maintenances. The unit will usually deliver lower power than normal if this is the case. Please contact your service representative for assistance.

DAILY MAINTENANCE

Use standard dental disinfectant to wipe down the handpiece after each procedure. Do not use bleach or abrasive cleansers. Be careful to prevent water from entering the unit, especially around the fiber optic handpiece connectors.

Clean the tips before and after every use to maximize their useful life. (See Tip Cleaning Instructions for details)

TRANSPORTATION

The Waterlase iPlus is susceptible to misalignment if not handled properly. The unit should ALWAYS be packed inside of its shipping crate when transported from one location to another. While the unit is semiportable, and may be rolled from one operatory to another inside of the same office, care should be taken when pushing the unit over doorway thresholds and other bumps or objects on the ground.

Do not roll the unit outside of the office building, across a road or over any other rough surface. Do not place the unit into a pick-up truck, van or other moving machine for transportation unless it is completely packaged inside of its shipping crate.

Once crated, the unit should be transported by fork lift or pallet jack, and should never be laid on its side, dropped or banged.

If you have any questions regarding transportation please call your local representative.

STORAGE

The Waterlase iPlus should be stored in a cool dry place when not in use. Storage temperature should be 15° to 30°(59°F to 86°F), relative humidity 20 to 80%. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

The Waterlase iPlus was shipped inside of a custom shipping crate. Please save and store the crate in a cool dry place. The unit must not be transported unless packaged inside of the crate.

12 Calibration

Calibration requires specialized equipment, and is to be performed only by a trained service engineer. The service engineer will follow this procedure:

- Connect an output power meter to the laser, using a test fiber. The power meter head should be 1 to 2 inches from the fiber tip.

- Using the software provided by Biolase, verify the test setup is complete.

- Begin the calibration routine. The software will vary the unit's output power settings and use the power readings from the meter to calibrate the power output monitoring settings.

- If required, the software will revise the unit's internal calibration settings to ensure power remains within ± 20%.

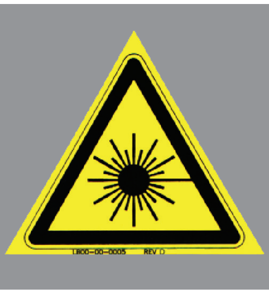
CALIBRATION SCHEDULE:

Power calibration is to be performed annually. The Service Engineer shall write the date of installation and subsequent power calibration dates in the table provided below:

Table 6: Installation and Calibration Dates

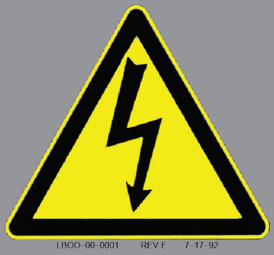
Installation Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician
Calibration Date:	Technician

Appendix A Labels



Laser Hazard Symbol

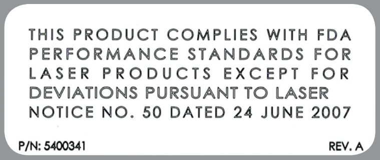
Location: Top cover of Laser head, directly above the Fiber Optic Connector. (Only visible during service)



High Voltage Hazard Symbol
(Only visible during service)

Locations:

- Top cover or Laser head, directly above the High Voltage input.
- PFN Board Capacitor
- Front Capacitor Bracket



THIS PRODUCT COMPLIES WITH FDA PERFORMANCE STANDARDS FOR LASER PRODUCTS EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 50 DATED 24 JUNE 2007

P/N: 5400341 REV. A

Certification

Location: Back Panel

DANGER

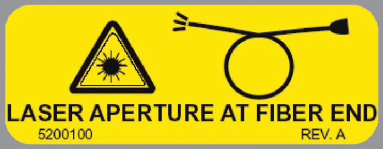
Invisible laser radiation
when open

AVOID EYE OR SKIN EXPOSURE
TO DIRECT OR
SCATTERED RADIATION

LB00-01-0008 REV B

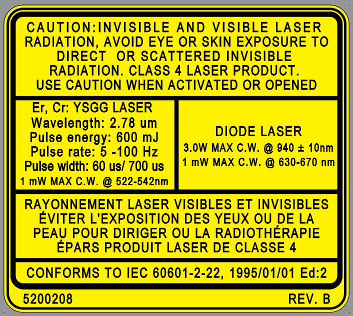
Non-Interlocked Protection Housing Warning

Location: Laser head, access plate. Accessible only during service proceedings.



Laser Aperture

Location: On the top cover, adjacent to Fiber Optic Connector


CAUTION:INVISIBLE AND VISIBLE LASER RADIATION, AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED INVISIBLE RADIATION. CLASS 4 LASER PRODUCT. USE CAUTION WHEN ACTIVATED OR OPENED

Er, Cr: YSGG LASER
Wavelength: 2.78 um
Pulse energy: 600 mJ
Pulse rate: 5 -100 Hz
Pulse width: 60 us/ 700 us
1 mW MAX C.W. @ 522-542nm

DIODE LASER
3.0W MAX C.W. @ 940 ± 10nm
1 mW MAX C.W. @ 630-670 nm

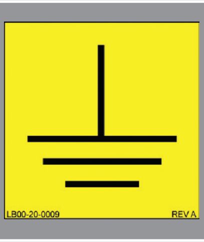
RAYONNEMENT LASER VISIBLES ET INVISIBLES ÉVITER L'EXPOSITION DES YEUX OU DE LA PEAU POUR DIRIGER OU LA RADIOTHÉRAPIE ÉPARS PRODUIT LASER DE CLASSE 4

CONFORMS TO IEC 60601-2-22, 1995/01/01 Ed:2

5200208 REV. B

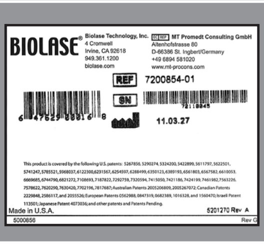
Laser Explanatory Label

Location: On top cover, adjacent to fiber optic connector



Ground

Location: Next to E1 ground terminal, inside unit.


BIOLASE®

Biolase Technology, Inc.
4 Cromwell
Irvine, CA 92618
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biolase.com

EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert/Germany
+49 6894 581020
www.mt-procons.com

REF 7200854-01

SN

11.03.27

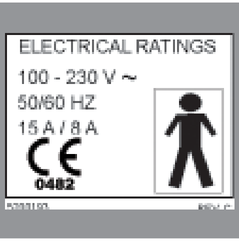
This product is covered by the following U.S. patents: 5267856, 5290274, 5324200, 5422899, 5611797, 5622501, 5741247, 5785521, 5968037, 6122300, 6231567, 6254597, 6288499, 6350123, 6389193, 6561803, 6567582, 6610053, 6669685, 6744790, 6821272, 7108693, 7187822, 7292759, 7320594, 7415050, 7421186, 7424199, 7461982, 7563226, 7578622, 7620290, 7630420, 7702196, 7817687; Australian Patents 2005206809, 2005267072; Canadian Patents 2229848, 2586117, and 2055526; European Patents 0562988, 0847319, 0682389, 1016328, and 1560470; Israeli Patent 113501; Japanese Patent 4073036; and other patents and Patents Pending.

Made in U.S.A. 5201270 Rev A

5000856 Rev G

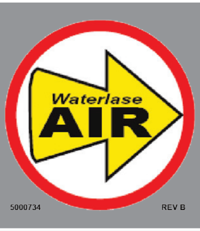
Identification

Location: Back Panel, above ventilation channels


ELECTRICAL RATINGS
100 - 230 V ~
50/60 HZ
15 A / 8 A
CE
0482

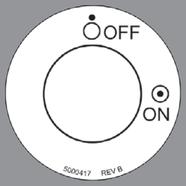
Electrical Ratings

Location: Next to Power cord connection



Air Label

Location: Base, rear of unit

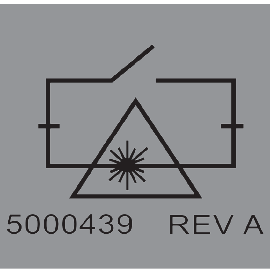


Key Switch

Location: Back panel

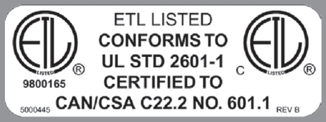
Appendix A Labels

(continued)


5000439 REV A

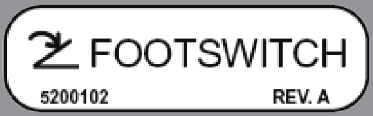
Remote Interlock Label

Location: Back Panel


ETL LISTED
CONFORMS TO
UL STD 2601-1
CERTIFIED TO
CAN/CSA C22.2 NO. 601.1
9800165
5000445
REV B
C

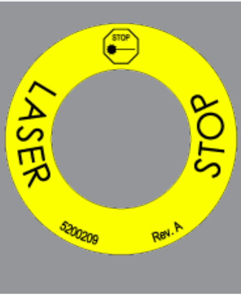
ETL Listed

Location: Back Panel


FOOTSWITCH
5200102
REV. A

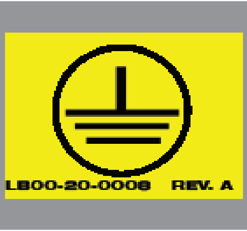
Footswitch Label

Location: Back Panel


STOP
LASER
STOP
5200209
Rev. A

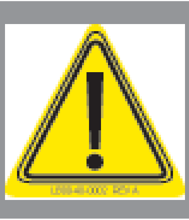
Emergency Stop Label

Location: Front Covert


LB00-20-0008
REV. A

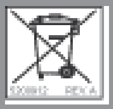
Protective Earth Ground

Location: Back Panel



Attention (Small)

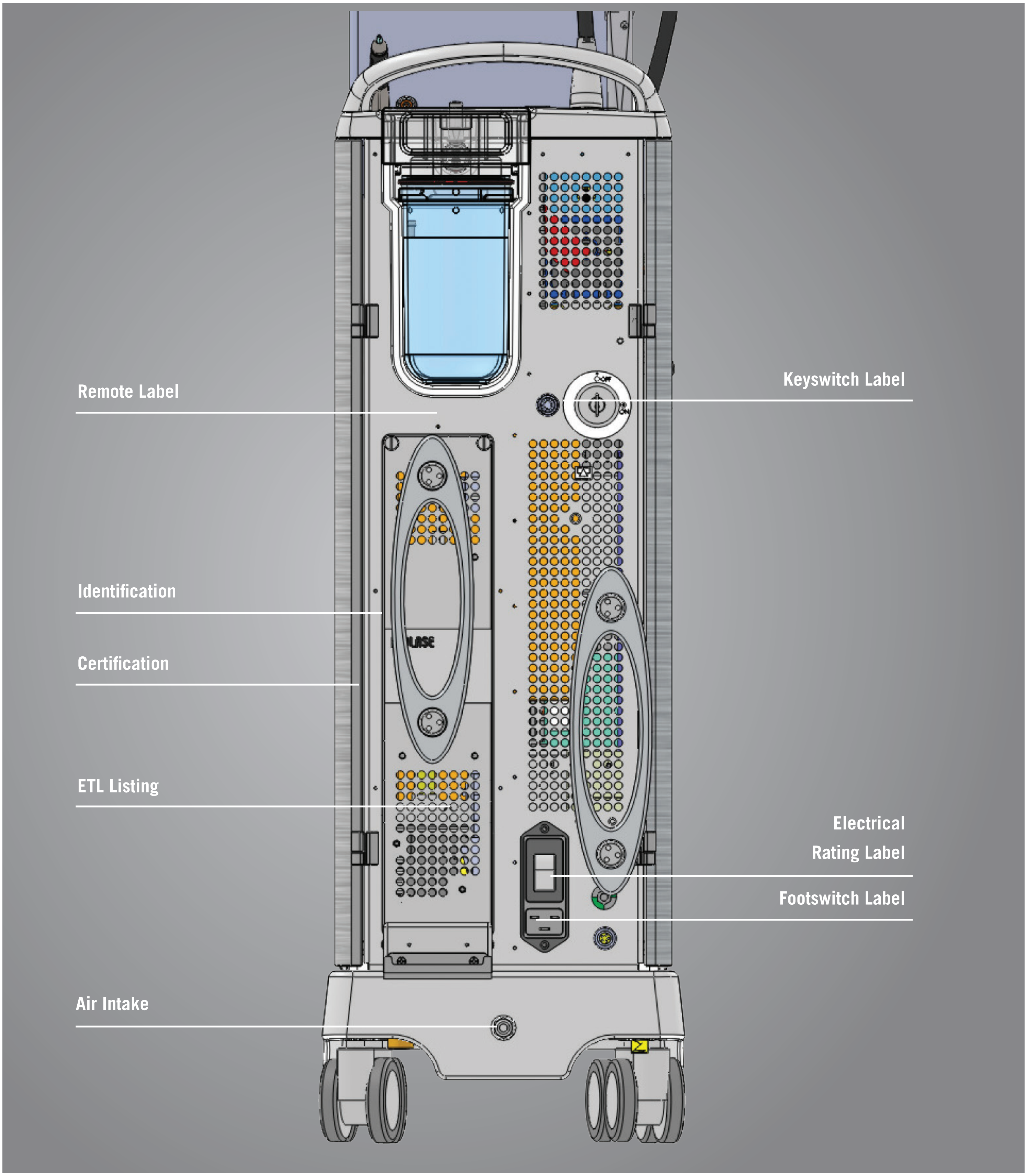
Location: Back Panel

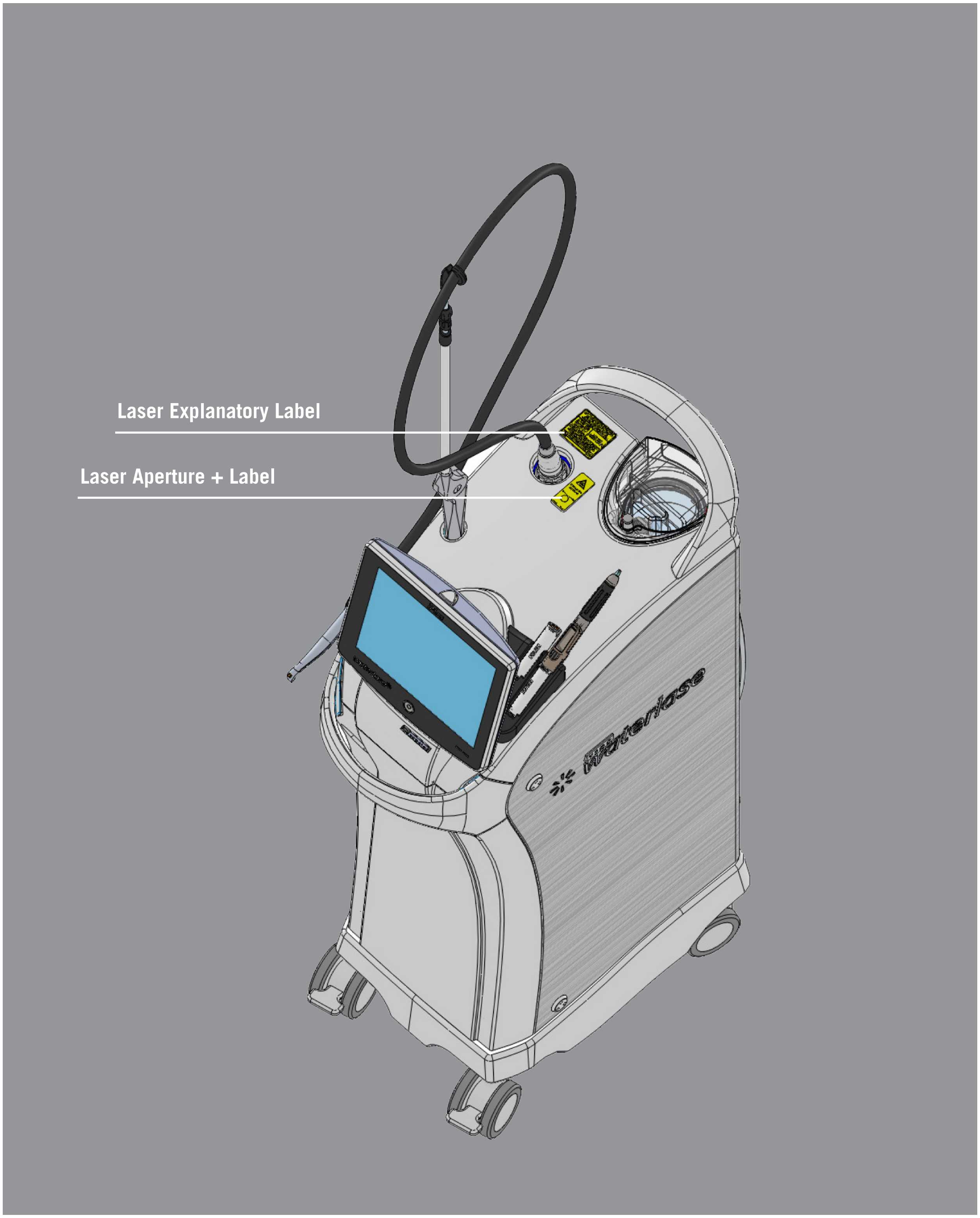


WEEE Label

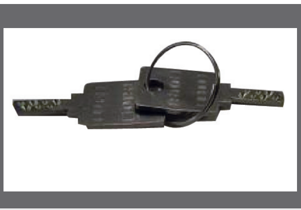
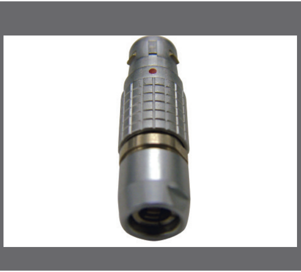
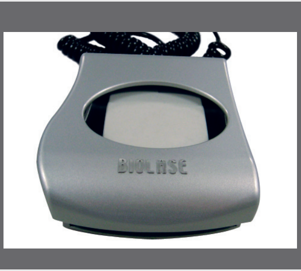
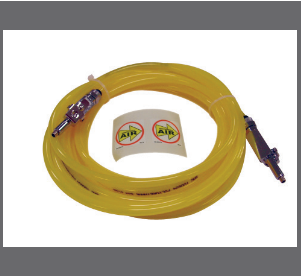
Location: Back Panel

(continued)


Remote Label
Identification
Certification
ETL Listing
Air Intake
Keyswitch Label
Electrical
Rating Label
Footswitch Label


Laser Explanatory Label
Laser Aperture + Label
Waterlase

Appendix B Accessories

KEYS	
REMOTE INTERLOCK	
FOOTSWITCH	
POWER CORD (USA)	
POWER CORD (EUROPE)	
AIR HOSE	

Appendix C Clinical Procedure Guidelines

PERIODONTAL THERAPY CLINICAL PROTOCOL

WARNINGS & PRECAUTIONS:

Eyewear: Doctor, patient, assistant and all others inside the operatory must wear appropriate laser protective eyewear for the 2.78 μm wavelength (OD 4). Use caution when using the tip inside the periodontal pocket. Excessive force could break the tip and inconvenience your patient. Laser protective magnification loupes are recommended for this procedure.

Do not direct air or spray toward tissue that may entrap air or water. Exercise caution when working inside the pocket without continuous water flow. Hard tissue structures that come in immediate contact with the laser energy in the absence of water could be damaged. Make sure to maintain a consistent water flow during the entire treatment, especially in the deeper areas of the pocket.

PROCEDURE

After routine periodontal evaluation through radiographic and clinical examination and assessment of probing depth, gingival recession, clinical attachment level, hyperplasia, bleeding on probing, plaque, suppuration, bone loss, furcation and mobility, proceed with the following steps:

STEP 1: ANESTHESIA

Apply anesthetic to the treatment site as needed. Topical anesthetic is usually adequate.

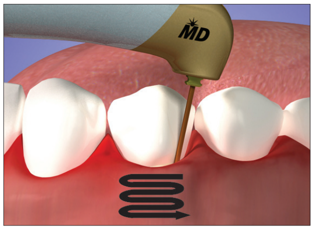
STEP 2: TROUGHING AND INNER EPITHELIUM LINING

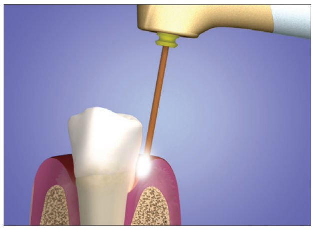
Step 2	Tip	Power	Pulse Rate	Air	Water	Mode
Troughing & Inner Epithelium Removal	RFPT5-14	1.5W	30Hz	11%	20%	H

SELECT SETTINGS AS PROVIDED IN THE TABLE ABOVE, USING A GOLD HANDPIECE

Place tip in contact with the gingival crest, parallel to the long axis of the tooth. Activate laser and start moving along the gingival margin to prepare a trough all the way to the crest of the bone. This trough will allow for increased visibility and access and to initiate removal of diseased epithelium lining. The radial and forward cutting action of this tip allows for effective separation and removal at the same time of the inflamed and diseased epithelium lining. The narrow tip glides easily to allow minimally invasive treatment of the entire epithelium lining all the way to the bottom of the pocket.

Alternatively, a bottom-up technique can be used in which the laser is fired only when moving the tip coronally. The protocol is optimized for safety and efficacy using either one of the techniques.





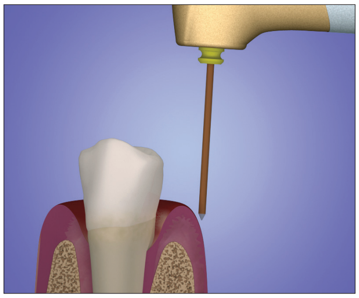
STEP 3: CALCULUS REMOVAL

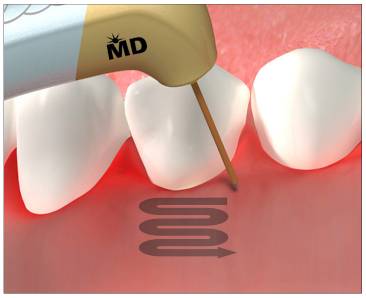
Step 3	Tip	Power	Pulse Rate	Air	Water	Mode
Calculus Removal	RFPT5-14	1.5W	30Hz	11%	20%	H
Root Surface Smoothening	RFPT5-14	1.5W	50Hz	11%	20%	H

Proceed with the mechanical removal of calculus using preferred hand and/or ultrasonic scalers. After gross calculus removal, remove calculus using the laser using the same settings provided in the previous step. To remove calculus from the root surface, aim the laser tip 5 to 15 degrees from the root surface. Move the tip in the same pattern as used to remove epithelium lining. Make enough passes to cover the entire root surface. Use a curette to insert into the pocket and push the gingiva away and with loupes, visualize the root surface. The surface has to look clean and free of any calculus deposits. Use the Root Surface Smoothening setting to refine the root surface to promote new attachment. Use the same pattern as used for calclus removal. Make enough passes to cover the entire root surface

STEP 4: OUTER EPITHELIUM LINING REMOVAL

Step 4	Tip	Power	Pulse Rate	Air	Water	Mode
Outer Epithelium Removal	RFPT5-14	1.5W	30Hz	11%	20%	H





Remove the outer epithelium using the same tip and laser settings provided in the Step 3. Position the tip parallel to and approximately 1 mm away from the outer gingiva. Angle the end of the tip slightly toward the surface. Activate the laser and move the tip over a 5 mm area from the gingival margin apically. The tissue surface is altered only enough to disrupt the epithelium layer, without significant tissue removal.

After removing the soft tissue, proceed with root surface preparation. Use your preferred conventional instrumentation and technique to perform this next step.

STEP 5: PRESSURE CLOT

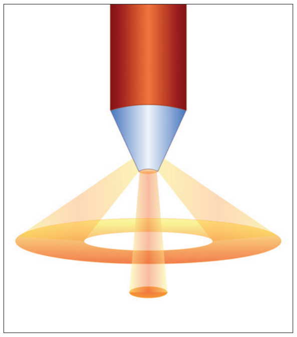
Insert a curette into the pocket to push the gingiva away and visualize the root surface. The surface should be clean and free of any calculus deposits. Applying external pressure should produce a thin layer blood clot inside the pocket. Hold and press a wet gauze in place over the outer area of the pocket for approximately 3 minutes to achieve this effect. Seal the clot within the sulcus by applying a barrier such as surgical glue (cyanoacrylate) along the gingival margin using a pipette. This seal is necessary to provide a barrier from external debris that might interfere with proper initiation of healing of the treated pocket. The first probing should be performed 3 months after the treatment.

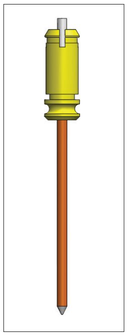
POST-OPERATIVE PATIENT INSTRUCTIONS

Do not to use a toothbrush for the first 24 hours after the procedure. Rinse with Peridex™ or other chlorhexidine solution two times per day for 2 weeks post-treatment. After 24 hours, start brushing again using a soft-bristle toothbrush and toothpaste, floss daily, and use an over-the-counter mouthwash rinse after the 2-week Peridex regimen. Schedule follow-up visits, including the first probing at 3 months. Some offices bring the patient back on a routine basis for coronal polishing and post-operative evaluation prior to the 3-month follow-up.

SINGLE USE NON-STERILE TIPS INCLUDED

1. Use only as specified in this guide.
2. Tip may break if excessive force is applied.
3. Dispose of tip in sharps container after single use.





Specifications	RFPT5-14
Tip Diameter	580µm
Tip Length	14mm
Max Power of Operation	4.0W
Calibration Factor	0.80

* Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe the clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, air and water settings, tip type and duration of operation) and to make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

ENDODONTIC THERAPY CLINICAL PROTOCOL

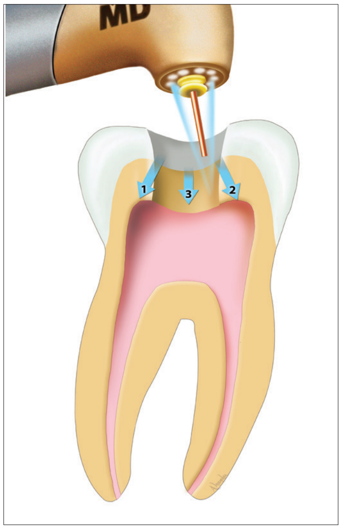
WARNINGS & PRECAUTIONS:

Eyewear: Doctor, patient, assistant and all others inside the operatory must wear appropriate laser protective eyewear for the 2.78 µm wavelength (OD 4). Clinical Use: The Endolase RFT™ system is suited for straight and slightly curved canals. Before proceeding with any endodontic treatment, a careful review of Contraindications, Precautions and Warnings, proper clinical training and practice on extracted teeth is recommended. Use caution when using tips through narrow and curved passages at all times. Forcing a tip through a narrow curved or obstructed canal could results in tip breakage and/or perforation. Activate the laser only when moving the tip upward coronally.

STEP 1: *ACCESS PREPARATION*

All settings provided are for use with the Gold Handpiece.

1. Access is prepared using the MZ5 ZipTip™ (6mm).
2. Select settings listed in the table below. Angle the tip 30-45° to the long axis of the tooth to cut enamel effectively.
3. Lower power setting or defocus the beam to cut through dentin.
4. Use the MZ5 for removal of pulp. Select "pulp removal" settings (see table below) to remove vital/non-vital pulpal tissue.



Appendix C Clinical Procedure Guidelines

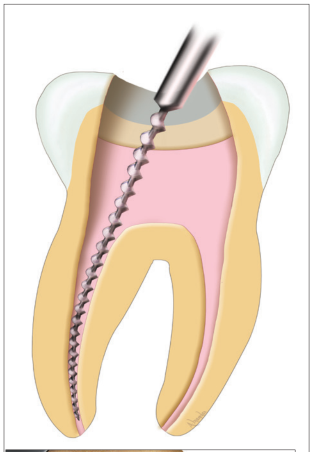
(continued)

Step 1	Tip	Power	Pulse Rate	Air	Water	Mode
Access	MZ5	4.5-5.5 W	15/20 Hz	60%	30%	H

Step 1	Tip	Power	Pulse Rate	Air	Water	Mode
Pulp Removal	MZ5	.75-1.0 W	20 Hz	2-11%	7-11%	H

STEP 2: *CONVENTIONAL INSTRUMENTATION*

1. Estimate the working length following standard protocol.
2. Start instrumentation using K-files or a combination of K-files and rotary files to enlarge and shape the canal.
3. Apical instrumentation is performed to at least a size 30 K-file to allow the RFT2 tip to reach the apex.

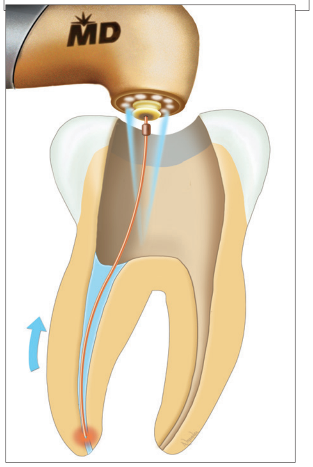


* Always start treatment at the lowest power setting for the specific tissue and increase as required. Closely observe the clinical effects and use your judgment to determine the aspects of the treatment (technique, proper power, air and water settings, tip type and duration of operation) and to make appropriate power, air and water adjustments to compensate for varying tissue composition, density and thickness.

STEP 3: *CLEANING & ENLARGEMENT*

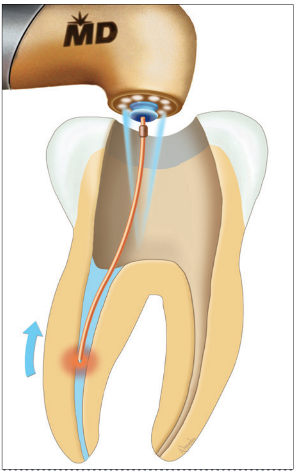
RFT2

1. Use the RFT2 to perform apical and partial coronal 2/3 cleaning.
2. Place tip into handpiece and select settings from the table below.
3. Fill canal with sterile solution.
4. Insert RFT2 (1) mm short of the apex. (Use the rubber slider on the tip as a depth indicator.)
5. Activate laser and start moving the tip coronally at approximately 1 mm/s. Maintain tip in contact with the side surface of the canal wall during the entire apical to coronal pass.
6. Repeat steps 4 and 5 one or two more times to ensure that the entire inner-canal has been cleaned.



RFT3

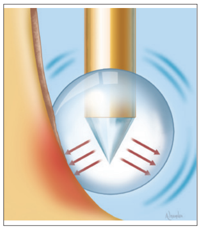
7. Use the RFT3 to perform final cleaning of the coronal 2/3.
8. Place tip into the handpiece and select settings from the table below.
9. Fill canal with sterile solution.
10. Insert RFT3 at the junction between apical and middle third.
11. Activate laser and start moving the tip coronally at approximately 1 mm/s.
Use the same technique as step 5.
12. Re-insert tip and perform an additional pass over the same area.
13. Repeat Steps 10 through 12 three more times to ensure cleaning of the remaining coronal 2/3.



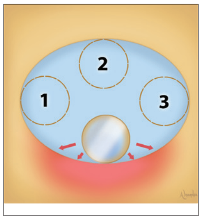
(continued)

Step 3	Tip	Power	Pulse Rate	Air	Water	Mode
Cleaning & Enlargement	RFT2	1.25 W	50 Hz	34%	24%	H

Step 3	Tip	Power	Pulse Rate	Air	Water	Mode
Cleaning & Enlargement	RFT3	1.25 W	50 Hz	34%	24%	H



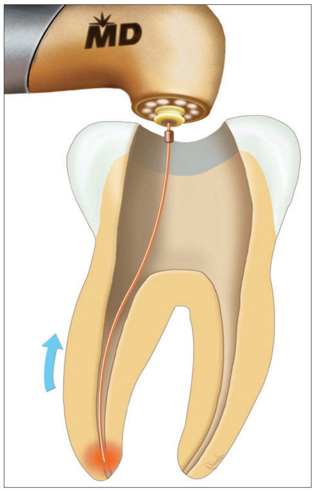
Hydrophotonic effect



Tip position during different passes

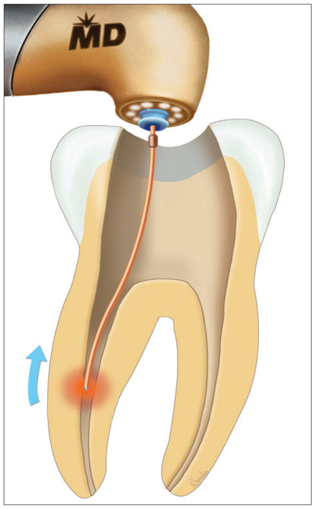
STEP 4: *DISINFECTION*

RFT2



1. Use the RFT2 to perform disinfection of the apical and partial coronal 2/3.
2. Place tip into handpiece and select settings from the table below. This procedure is performed with 10% air flow and no water.
3. Insert RFT2 (1) mm short of the apex.
4. Activate laser and start moving the tip coronally, at approximately 1 mm/s. Maintain tip in contact with the side surface of the canal wall during the entire pass. Use a brushing technique to deliver YSGG laser energy to the surface.
5. Re-insert tip immediately and perform an additional pass over the same area.
6. Repeat steps 3 through 5, two to three more times to ensure disinfection of apical and partial coronal 2/3.

RFT3



7. Use the RFT3 to perform final disinfection of the coronal 2/3.
8. Place tip into handpiece and select settings from the table below. Use 10% air flow as before (see step 2).
9. Insert RFT3 at the junction between apical and middle third.
10. Activate laser and start moving the tip coronally, at approximately 1mm/s. Use the same techniques as step 4 (disinfection).
11. Re-insert tip immediately and perform an additional pass over the same area.
12. Repeat steps 9 through 11, three to four more times to ensure disinfection of the remaining coronal 2/3.

OBTURATION & RESTORATION PLACEMENT

Use any of your preferred techniques and materials to fill the canal and restore the tooth. Single Use Non-Sterile Tips Included

1. Use only as specified in this guide.
2. Tip may break when excessive force is applied.
3. Dispose in sharps container after single use.

Step 4	Tip	Power	Pulse Rate	Air	Water	Mode
Disinfection	RFT2	.75 W	20 Hz	10%	Off	H

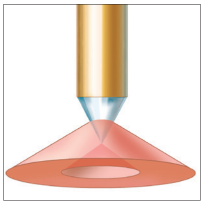
Step 4	Tip	Power	Pulse Rate	Air	Water	Mode
Disinfection	RFT3	.75 W	20 Hz	10%	Off	H

Appendix C *Clinical Procedure Guidelines*

(continued)

CALIBRATION FACTOR

	RFT2	RFT3
Tip Diameter, µm	275	415
Tip Length, mm	25, 21	21, 17
Max Power of Operation [Watt]	4.0	4.0
Calibration Factor *	0.55	0.85



RFT2

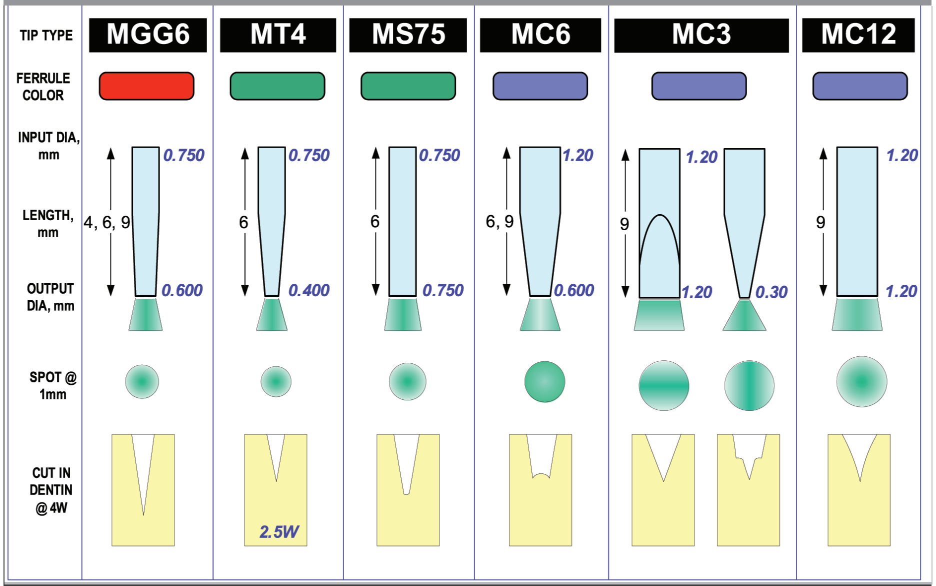
RFT3

* Laser Power recommended with procedural steps are values on the display. The actual power output can be calculated by multiplying that value by the Calibration Factor for each tip.

NOTE: Clinicians who are conservative of tooth structure and wish to keep the tapered shape of the canal to a minimum may find this laser procedure sufficient for such goals. However, if the goal is to achieve a more tapered shape to accommodate the wide Gutta-Percha points, additional instrumentation may be necessary.

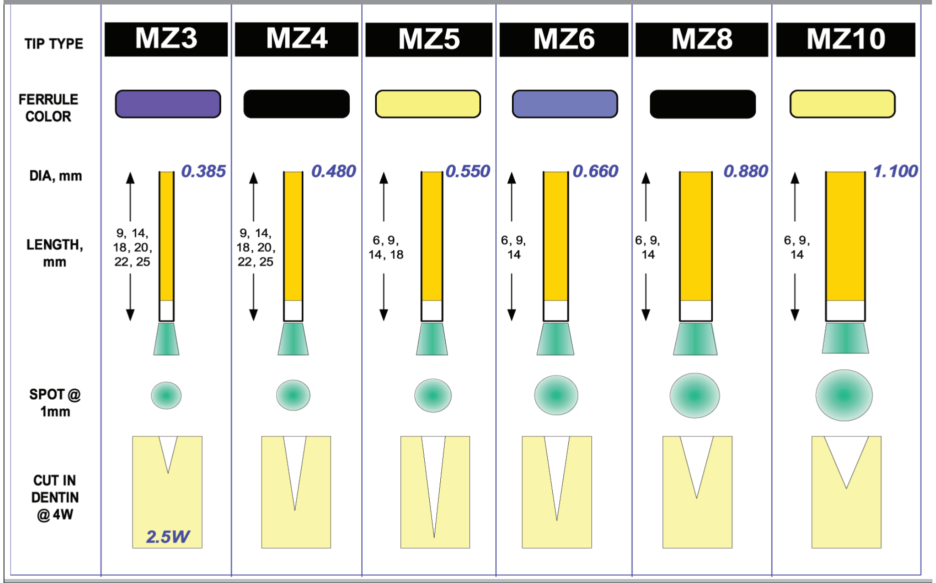
Appendix D Tips: Suggested Clinical Specifications

SAPPHIRE TIPS GUIDE



TIP TYPE	MGG6	MT4	MS75	MC6	MC3	MC12
FERRULE COLOR	🟥	🟩	🟩	🟦	🟦	🟦
INPUT DIA, mm	0.750	0.750	0.750	1.20	1.20	1.20
LENGTH, mm	4, 6, 9	6	6	6, 9	9	9
OUTPUT DIA, mm	0.600	0.400	0.750	0.600	1.20 0.30	1.20
SPOT @ 1mm						
CUT IN DENTIN @ 4W		2.5W				

“Z” TIPS GUIDE



TIP TYPE	MZ3	MZ4	MZ5	MZ6	MZ8	MZ10
FERRULE COLOR	🟪	⬛	🟨	🟦	⬛	🟨
DIA, mm	0.385	0.480	0.550	0.660	0.880	1.100
LENGTH, mm	9, 14, 18, 20, 22, 25	9, 14, 18, 20, 22, 25	6, 9, 14, 18	6, 9, 14	6, 9, 14	6, 9, 14
SPOT @ 1mm						
CUT IN DENTIN @ 4W	2.5W					

TIP SETTINGS: WATERLASE IPLUS / MD GOLD HANDPIECES

Tip Type	Ferrule Color/ Diameter (µm)	Lengths (µm)	Gold Handpieces		Tissue Types
			Calibration Factor*	Maximum Power (W)	
Z - Glass Tips					
RFT2	200	21, 25	0.55	4.0	Root Canal
MZ3	320	9, 14, 18, 20, 22, 25, 28	0.85	4.0	Root Canal, Soft Tissue
RFT3		17, 21			Root Canal
MZ4	400	3, 6, 9, 14, 18, 20, 22, 25, 28	.90	4.0	All Types
MZ5	500	3, 6, 9, 14	.95	4.0	All Types
RFPT5		10, 14		6.0	Bone, Soft Tissue
MZ6	600	3, 6, 9, 14	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MZ8	800	3, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MZ10	1000	3, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
Sapphire Tips					
MT4	400	6	1.00	2.5	Enamel, Dentin, Soft Tissue
MGG6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MS75	750	6	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC3	300 x 1200	9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC6	600	4, 6, 9	1.00	No Limit	Enamel, Bone, Dentin, Soft Tissue
MC12	1200	9	1.00	No Limit	Bone, Dentin, Soft Tissue

Appendix D Tips: Suggested Clinical Specifications

(continued)

INDICATIONS FOR USE

Tip Type	Soft Tissue	Hard Tissue
Z – Glass Tips		
RFT2	N/A	Root canal debridement, cleaning and disinfection
MZ3	Sulcular debridement; Laser soft tissue currettage	Removal of granulation tissue
RFT3	N/A	Root canal debridement, cleaning and disinfection
MZ4	Same as MT4. Sulcular debridement; Laser soft tissue currettage	Same as MT4
MZ5	Combines applications of MZ4 and MZ6 tips	Combines applications of MZ4 and MZ6 tips
RFPT5	Decontamination and ablation of soft tissue in periodontal pockets	Cleaning the root surface, similar to MZ5
MZ6	Same as MGG6	Same as MGG6
MZ8	Same as MGG6	Same as MGG6
MZ10	Same as MGG6	Same as MGG6
Sapphire Tips		
MT4	Frenectomy and frenetomy; Gingival troughing; Gingivectomy; Gingivoplasty; Gingival incision and excision; Removal of pathological tissues; Incision and drainage of periapical abscessess; Full, partial and split thickness flap preparation	Excavation of pits and fissures for placement of sealants; Pits and fissures/caries removal
MC3	Most applications are the same as for MT4 and MGG6 tips, taking into consideration "flat" shape of the tip	Cutting, contouring, shaving and resection of oral osseous tissue (bone)
MGG6	Same as MT4; Excisional and incisional biopsies; Exposure of unerupted teeth; Fibroma removal; Hemostasis; Implant recovery; Incision and drainage of abscesses; Leukoplakia; Operculectomy; Oral papillectomy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores; Vestibuloplasty	Cavity preparation I-V; Caries removal; Hard tissue roughening or etching; enameloplasty; Tooth preparation to access to a root canal; Cutting, contouring, shaving and resection of oral osseous tissue (bone); Osteotomy, ostectomy, osteoplasty and osseous recontouring; Cutting bone to prepare a window access to the apex of the root; Apicoectomy; Root end preparation for retrofill
MS75	Same as MGG6	Same as MGG6
MC6	Same as MGG6, considering more "shallow" cutting profile of tip	Same as MGG6, considering more "shallow" cutting profile of tip
MC12	Same as MGG6 and MG6, considering bigger surface area and significantly "shallower" cutting profile of tip	Same as MGG6, considering bigger surface area and significantly "shallower" cutting profile of tip

****Calibration Factor:** Actual power emitted from the tip = displayed power multiplied by the Calibration Factor. Applicable to entire range of power settings for the tip type.

Cautions: If a reduction in cutting efficiency is observed, replace the tip. Failure to replace the tip correctly could result in damage of the tip or the handpiece mirror. The tips have limited lifetime therefore damage of the delivery system attributed to overuse of the disposable tip may not be covered by warranty.

IMPORTANT: Federal law restricts this device to sale by or on the order of a dentist or a physician. Only licensed professionals who have successfully completed training should use the laser and accessories. Always start treatment at the lowest power setting and increase as required. Closely observe the clinical effects and use your professional judgment to determine the aspects of the treatment (technique, proper power settings, air and water settings, tip type and duration of the operation) and to make appropriate adjustments to compensate for varying tissue composition, density and thickness.

Appendix E Electromagnetic Compatibility

CAUTION: Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.

Accessories: Medical grade power cord, maximum length 10ft (2.44 meters) (Biolase part number 2000204).

Footswitch: includes shielded, coiled footswitch cable, footswitch, 5 conducting wires. (Biolase part number 6200150)

WARNING: The use of accessories, other than those specified, except those supplied or sold by Biolase Technology as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the model Waterlase iPlus.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Waterlase iPlus is intended for use in the electromagnetic environment specified below. The customer or the user of the Waterlase iPlus should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The model Waterlase MD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The model Waterlase iPlus is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Appendix E Electromagnetic Compatibility

(continued)

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

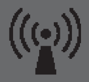
The model Waterlase iPlus is intended for use in the electromagnetic environment specified below. The customer or the user of the model Waterlase iPlus should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment. Input/output that does not apply because the footswitch cable length is less than 3 meters
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_r (>95% dip in UT) for 0.5 cycle 40% U_r (60% dip in UT) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% U_r (>95% dip in U_r) for 5 seconds	<5% U_r (>95% dip in UT) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% U_r (>95% dip in U_r) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Waterlase iPlus requires continued operation during power mains interruptions, it is recommended that the model Waterlase iPlus be powered from an uninterrupted power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_r is the A.C. mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The model Waterlase iPlus is intended for use in the electromagnetic environment specified below. The customer or the user of the model Waterlase iPlus should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the model Waterlase iPlus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Waterlase iPlus is used exceeds the applicable RF compliance level above, the Waterlase iPlus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Waterlase iPlus.

B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE WATERLASE iPLUS

The Waterlase iPlus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Waterlase iPlus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Waterlase iPlus as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz d = 1.2√P	**80 MHz to 800 MHz** d = 1.2√P	**800 MHz to 2,5 GHz** d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Founded in 1986, BIOLASE, Inc. specializes in lasers for medicine and dentistry that feature proprietary and patented technologies for minimally invasive surgeries, reducing pain and improving clinical results.

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